

SEP 13 2007

TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
NHS-0010

Re Application Of: Natan Bauman

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/773,731	February 5, 2004	Walter F. Briney III	23413	2615	8615

Invention: HEARING AID SYSTEM

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

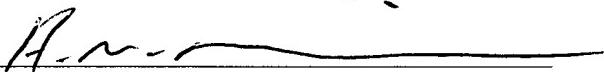
July 31, 2007

- Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: \$250.00

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Signature

Dated: September 11, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2615
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM) Examiner:
) Walter F. Briney III
)

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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1) REAL PARTY IN INTEREST

The real party in interest is Vivotone Hearing Systems, LLC.

(2) RELATED APPEALS AND INTERFERENCES

Co-owned U.S. Patent Application Serial No. 10/325,529 has a co-pending appeal.

(3) STATUS OF CLAIMS

A Final Office Action issued on July 6, 2007 rejecting claims 1-12, 19, 21-24, 26-29, 35-38, 40 and 42-67. Claims 1-12, 19, 21-24, 26-29, 35-38, 40 and 42-67 are currently being appealed in the present application. Claims 13-18, 20, 25, 30-34, 39 and 41 stand as cancelled.

(4) STATUS OF AMENDMENTS

There are no after-final amendments.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The presently appealed claims describe an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal such that it provides an open ear configuration.

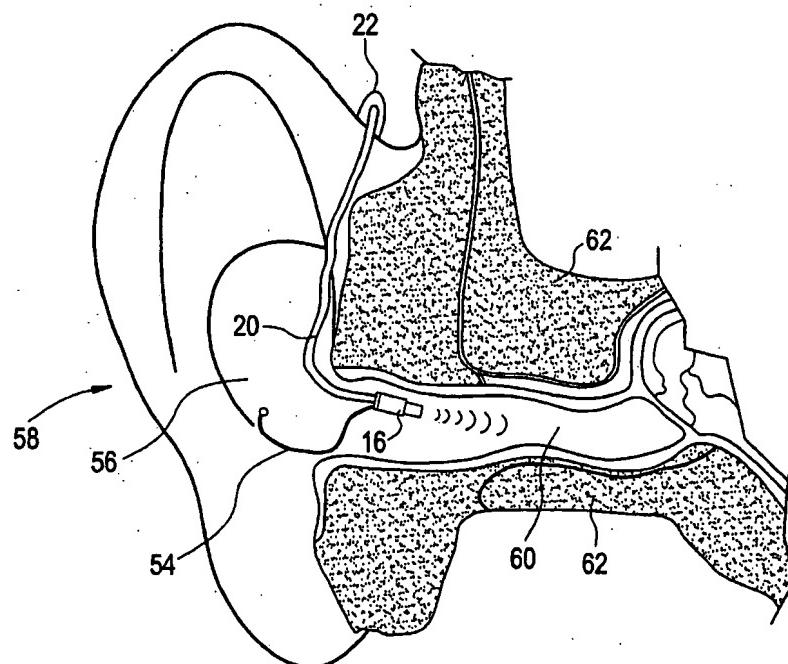
Both of the independent claims (1 and 36) require as shared limitations:

a microphone sampling position located externally of an ear canal of a user,

a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration,

wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

FIG. 5



With regard to the above, reference is made to the Applicant's FIGURE 5, which shows the receiver 16 suspended within the ear canal in an open ear configuration. A connector 22 of the behind the ear (BTE) unit 52 (see FIGURE 4) is illustrated above and behind the user's ear, with a connector 20 providing electrical connection between the BTE and the receiver. As is noted in paragraph 25, a microphone 27 is provided in or on the BTE. Also as noted in paragraph 33, the BTE includes a hearing aid amplifier and sound processing component 68.

In addition to the shared limitations described above, independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a

portion of human ear audible frequencies. This is referenced at paragraph 8 and, with regard to the experimental data included within the specification, at paragraph 40.

In addition to the shared limitations described above, independent claim 36 further requires that the receiver have a maximum lateral dimension that is less than fifty percent of the maximum lateral dimension of a user's ear canal. Reference is made again to FIGURE 5, which illustrates lateral dimensions of both the receiver 16 and the user's ear canal. Reference is also made to paragraph 31 and FIGURE 2, which describes exemplary relationships between lateral dimensions of the receiver 16 and of the ear canal.

(6) GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

Various legal errors of the Examiner will first be identified, followed by specific reference to the iterated rejections of the Examiner:

- (A) The Examiner fails to give any weight to evidence of secondary considerations of non-obviousness;
- (B) The Examiner claims that expert testimony itself is not valid evidence in support of non-obviousness, but must instead be supplemented by separate evidence;
- (C) The Examiner improperly contends that motivation to modify references may be reasoned from alleged desires of "one of ordinary skill in the art" to avoid patent claim infringement (i.e., removal of a required claim component to avoid infringing the claim);
- (D) The Examiner improperly contends that evidence of copying is not valid without providing evidence that, prior to copying, the competition conducted extensive research into finding their own solution;

- (E) The Examiner did not recognize that the weight of the secondary consideration evidence obviated the proposed prima facie cases of obviousness;
- (F) Claims 1-7, 40, 42-53 and 59-63 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,987,146 to Pluvinage et al. (hereinafter “Pluvinage”);
- (G) Claims 8, 26-29, 35-37 and 54-57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the “Knowles product catalog”;
- (H) Claims 9 and 38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog and further in view of U.S. Patent No. 5,960,093 to Miller (hereinafter “Miller”);
- (I) Claims 64-67 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of U.S. Patent No. 4,425,481 to Mansgold et al. (hereinafter “Mansgold”);
- (J) Claim 1 has been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2004/0010181 to Feeley et al. (hereinafter “Feeley”) in view of U.S. Patent Application Publication NO. 2003/0002700 to Fretz et al. (hereinafter “Fretz”) and further in view of Pluvinage;
- (K) Claims 19, 21-24 and 58 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of “GN Magazine from January 2005” in view of the “ReSound AiR

pamphlet from September 2003” in view of the “GN ReSound article from April 2003”; and

- (L) Claims 36-38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of the Knowles product catalog in view of Miller;
- (M) Claims 10-12 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement;
- (N) Claims 1-12, 19, 21-24, 26-29, 35, 40, 42-55, 58-60, 62, 64 and 66 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.
- (O) Even assuming (simply for the sake of argument) that a viable *prima facie* case of obviousness has been made out, the claims are patentable by virtue of the overwhelming evidence of secondary considerations.

(7) ARGUMENT

(A) *The Examiner fails to give any weight to evidence of secondary considerations.*

The Applicants have submitted a large body of commercial success evidence to rebut any potential *prima facie* cases. As is noted in the Evidence Appendix, Vivotone President Leon Hirsch submitted numerous declarations detailing the commercial success of the Vivotone open ear hearing aid (which Vivotone enjoyed despite extremely minimal advertising), copying by numerous large competitors in the industry, laudatory statements by competitors that directly relate to the advantageous aspects of the Applicant’s claimed open ear configuration, and the elimination of a long felt need in the industry by the introduction of Vivotone’s open ear system.

During prosecution, the Examiner failed to give weight to the substantial body of submitted secondary consideration evidence. Though the Applicant argued this error, the

Applicant further submitted declarations by field experts Drs. Glaser and Berlin as further support for the evidence of secondary consideration. However, the Examiner persisted in failing to give weight to the evidence of secondary consideration.

It is noted that the Board and the Examiner must consider and give weight to the secondary consideration evidence on record.

In *In Re John B. Sullivan, et al.* (August 29, 2007), the Federal Circuit vacated the Board's decision because it failed to give any weight to the rebuttal evidence of record. Most relevant to the resolution of the appeal, was the Board's statement in a footnote that:

"The remainder of appellants [sic] arguments on this record, in addition to the Declarations of record, relate to the use of the claimed composition as an anti-venom. Since we have placed not [sic] weight on the intended use of appellants' composition we do not address these arguments or the Declarations."

The appellate court accepted that a *prima facie* case of obviousness had been set forth by the Examiner. However, with regard to the rebuttal evidence, the court noted that:

The Board stated in a footnote that the declarations of record relate only to the use of the claimed composition as an anti-venom, and thus the Board expressly declined to give any meaningful consideration to them. *Sullivan*, No. 2006-0220, slip op. at 13 n.7. As stated above, when an applicant puts forth relevant rebuttal evidence, as it did here, the Board must consider such evidence. The claimed composition cannot be held to have been obvious if competent evidence rebuts the *prima facie* case of obviousness. By failing to consider the submitted evidence, the Board thus committed error.

Moreover, the Board was mistaken to assert that the declarations only relate to the use of the claimed composition. The declarations do more than that; they purport to show an unexpected result from use of the claimed composition, how the prior

art taught away from the composition, and how a long-felt need existed for a new anti-venom composition. While a statement of intended use may not render a known composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence. Had the Board considered or reviewed the declarations in any meaningful way, it might have arrived at a different conclusion than it did.

Furthermore, the Board's focus on the intended use of the claimed composition misses the mark. The Board cites *In re Zierden*, 411 F.2d 1325 (CCPA 1969), for the proposition that a statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable. In that case, applicant conceded that his composition was distinguished from the composition disclosed in a prior art patent only by the statement of intended use. Our predecessor court held that that intended use for the known composition could not render the claim patentable. In this case, applicant does not concede that the only distinguishing factor of its composition is the statement of intended use and, in fact, extensively argues that its claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. Such a use and unexpected property cannot be ignored. See *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963) ("From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. . . . There is no basis in law for ignoring any property in making such a comparison."). The issue here is not whether a claim recites a new use, but whether the subject matter of the claim possesses an unexpected use. That unexpected property is relevant, and thus the declarations describing it should have been considered by the Board.

As is noted above, the purpose of secondary consideration evidence is rebuttal of a prima facie case of obviousness, and the evidence must be properly considered (*See Alco Standard Corp. v. Tennessee Valley Authority*, 1 USPQ2d 1337, 1344 (Fed. Cir.

1986), *cert. denied*, 483 U.S. 1052 (1987) (While “standing alone, the prior art provides significant support for the … contention that the … patent would have been obvious,” evidence of secondary considerations, including the solution of a long-felt need, served to “establish that [the] invention appearing to have been obvious in light of the prior art was not.”).

(B) The Examiner erroneously asserts that expert testimony itself is not valid evidence in support of non-obviousness, but must instead be supplemented by separate evidence.

The Examiner’s contends that the expert declarations do not constitute valid evidence in support of non-obviousness. This completely ignores the evidentiary nature of expert testimony. With specific regard to the Examiner’s Action of July 6, 2007 beginning at page 20, the Examiner categorically discounts every point made by the audiology expert, Dr. Glaser. Exemplary quotes are extracted from the Examiner’s July 6, 2007 action below:

at page 20, lines 9-10:

In paragraph 13, Dr. Glaser opens with the contention that Pluvinage requires sampling sound within the ear canal. This statement is made here without basis.

at page 20, lines 19-22:

In paragraph 14, Dr. Glaser reads Feeley as a teaching to occlude the ear canal despite the use of an “open mold.”…This appears to be a non sequitur.

at page 21, lines 13-15:

Dr. Glaser refers to a loss of market share, yet this is undocumented and all discussion is, therefore, moot.

at page 21, lines 15-16:

Again, talk is made of penetration into the marketplace, but this has not been documented…

at page 21, lines 17-18:

Dr. Glaser notes that advertising hearing aids is expensive, but offers no evidence.

at page 21, lines 18-21:

Dr. Glaser continues with a discussion of the Kirkwood reference, indicating that its market data is not germane to the Vivotone hearing aid since said hearing aid is not comparable. Again, this means no evidence concerning market success has been presented.

at page 22, lines 3-7:

Dr. Glaser finally concludes by stating “the Vivotone System is an advancement in that it rejects BTE-tube designs as well as the hybridized tube design of Pluvinage.” … there is no evidence of it rejecting the hybridized tube design of Pluvinage.

The Examiner’s treatment of Dr. Glaser’s testimony completely ignores the fact that each of Dr. Glaser’s statements are themselves evidence. For example, Dr. Glaser, as one of ordinary skill in the art (reference is made to Dr. Glaser’s substantial curriculum vitae, attached to Dr. Glaser’s declaration), after review of the Pluvinage reference, testified that the Vivotone System rejects the hybridized tube design of Pluvinage. This testimony constitutes documentary evidence of that fact. The Examiner may not, in the face of that evidence, claim that there is no evidence of the Vivotone System rejecting the hybridized tube design of Pluvinage.

The Examiner similarly treated other points of Dr. Glaser’s testimony, e.g., Dr. Glaser’s characterization of the marketplace, his discussion of Vivotone’s performance, including penetration into the marketplace and market share, his technical understandings of the patent references, etc. The Examiner improperly ignored the evidentiary value of Dr. Glaser’s expert testimony.

The Examiner similarly ignored the evidentiary value of Dr. Berlin's expert testimony, e.g.,:
at page 22, lines 15-17 (the Examiner discounts Dr. Berlin's technical understanding of the Pluvinage system and ignores his technical explanation):

In paragraph 6, Dr. Berlin states that Pluvinage requires a sound sampling tube "to control feedback and make its own probe mike measurements." However, no evidence of this can be found in the reference.

at page 23, lines 12-17 (again, discounting Dr. Berlin's technical understanding of how the hearing aid system described by Pluvinage necessarily worked):

In paragraph 8d, Dr. Berlin states that the wide-dynamic range compressor of Pluvinage could not operate without the second microphone tube: "the adaptations required of the processor were IMPOSSIBLE without the use and presence of the second sound tube." In essence, Dr. Berlin argues here that all ReSound hearing aids in the early 90s without the second sound tube of Pluvinage did not work.

This is totally absurd.

at page 23, lines 20-21:

In paragraph 9, Dr. Berlin argues just as Dr. Glaser does in paragraph 12 of his declaration. Ergo, this paragraph is unpersuasive for the same reasons.

at page 24, lines 1-4:

In paragraph 10, Dr. Berlin states that Feeley requires a mold while Fretz describes a conventional BTE-tube design. From this, he concludes that the configurations would cause much more insertion loss than the Vivotone hearing aid. This is a very powerful charge to make, but again is without any evidence.

at page 24, lines 7-10:

In paragraph 11, Dr. Berlin argues that the Vivotone device claimed is not comparable to other devices in a market sense, that it was copied and lost market

share, and spent little on advertising. These assertions were already treated *supra* regarding paragraph 16 of Dr. Glaser's declaration.

at page 24, lines 11-13:

In paragraph 12, Dr. Berlin cites advertising from the early 90's during the Gulf War; however, no evidence of the amount of money spent on and the success of such advertising is provided.

at page 24, lines 14-17:

In paragraph 13, Dr. Berlin states that Vivotone cannot be compared. Again, this means that no market data can be considered on the record, which renders any decision of market success a guessing game.

at page 25, lines 4-7:

Those sections of applicant's arguments that wholly depend on the declarations of Drs. Glaser and Berlin are not treated specifically below since the declarations have been found unpersuasive.

While we have reproduced a large number of the Examiner's categorical rebuttal of the expert declarations, we feel that it is illustrative of the Examiner's unwillingness to consider the evidentiary value of Drs. Glaser and Berlin's expert testimony. The evidentiary value of this expert testimony cannot be categorically dismissed.

(C) The Examiner improperly contends that motivation to modify references may be reasoned from alleged desires of "one of ordinary skill in the art" to avoid patent claim infringement (i.e., removal of a required claim component to avoid infringing the claim).

The Examiner contends that it is proper to find motivation to modify a patent reference by removing any limitation(s) that is recited in a claim. The Examiner's rationale is that "one of ordinary skill in the art" will want to remove that limitation (without reference to why the reference teaches and claims the limitation) BECAUSE by

doing so, the one of ordinary skill in the art will not infringe the claim. The Examiner’s “rule” has a few fatal/unlawful flaws: 1) the rule would allow an Examiner to take any reference and apply (in a rejection) a new teaching that is an opposite of what is taught by the four corners of the document (e.g., if the patent document teaches building an automobile (claimed product) by providing, in part, an engine (limitation A), the Examiner would, by his rationale, have a viable document that also teaches an automobile without an engine); and 2) the rule would require that one of ordinary skill in the art be willing and able to legally review the claims to determine how not to infringe.

Indeed, the Examiner’s assertions would mean that “one of ordinary skill in the art” would necessarily have to be a licensed patent attorney, having the training and ability to perform claim construction of claim terminology based on the specification and the prosecution history in order to understand whether a product that they might dispense would potentially infringe (assuming they even cared). To require “one of ordinary skill in the art” to be a patent lawyer goes completely against the plain language and purpose of looking to the understanding of “one of *ordinary* skill in the *art*” when assessing motivation to combine references or otherwise modify a teaching. In this case, the “*art*” is Audiology, not patent law. Further “one of *ordinary* skill” in Audiology is not a patent lawyer turned Audiologist, or an Audiologist turned patent lawyer; it is an Audiologist.

(D) The Examiner improperly contends that evidence of copying is not valid without providing evidence that, prior to copying, the competition conducted extensive research into finding their own solution.

At page 25 of the Examiner’s final action, lines 12-13, the Examiner indicates, “Absent the evidence of extensive research by competitors, the evidence is unpersuasive.” The Examiner improperly indicated that in order to sustain any claim of copying by others in the industry (as evidence of secondary considerations), the Applicant must additionally submit evidence that the competition conducted extensive research into finding their own solution before copying the invention. **This is not true.**

As we noted in previous responses, this would be impossible, considering that competitors **do not publish** their internal research and development plans and results.

Such a requirement would render the purpose of evidence of copying completely moot for purposes of examination in front of the Patent Office.

The Examiner may be referencing MPEP 716.06, which cites Dow Chemical without any comment:

Evidence of copying was persuasive of nonobviousness when an alleged infringer tried for a substantial length of time to design a product or process similar to the claimed invention, but failed and then copied the claimed invention instead. *Dow Chem. Co. v. American Cyanamid Co.*, 837 F.2d 469, 2 USPQ2d 1350 (Fed. Cir. 1987). This cite comment is specific to Dow Chemical; it does not define a test for all evidence of copying.

Note the Decision before the Board of Appeals in *Ex parte DONALD G. GILLIS and DANIEL JOHNSON*, Appeal No. 2004-1753, Application No. 09/524,086, page 5, <http://www.uspto.gov/go/dcom/bpai/decisions/fd041753.pdf>. In that decision, the Board noted that the Examiner improperly failed to consider the evidence of secondary consideration. With regard to the evidence of copying, the board cited a declaration of inventor Gillis that illustrated that major suppliers in the industry copied the applicant's invention. *The Board validated this evidence, but did not require evidence that those competitors conducted their own research and development prior to copying the applicant's invention.*

The Court in *Buildex Incorporated V. Kason Industries, Inc.*, also recognized that evidence of copying itself (without reference to failure of others) is viable in stating, "It is also significant that no one had designed a hinge like the 2850T for many years but that Kason introduced the 1263 shortly after the 2850T appeared." 665 F.Supp. 1021, 4 U.S.P.Q.2D 1803 (E.D. New York, 1987), citing *Allen Archery, Inc. v. Browning Manufacturing co.*, 819 F.2d 1087, 1092 (Fed.Cir.1987) (significance of copying); *Dow Chemical Co. v. American Cyanamid Co.*, 816 F.2d 617, 620 (Fed.Cir.1987) (same); *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1480 (Fed.Cir.1986)

(same); *cf. Panduit Corp. v. Dennison Manufacturing Co.*, 810 F.2d 1561, 1571 (Fed.Cir.1987) (defendant copied inventions).

Similarly, the Court in *Vandenberg v. Dairy Equipment Co.* indicated that “the copying of an invention may constitute evidence that the invention is not an obvious one.” 740 F.2d 1560, 1567 (Fed. Circ. 1984), citing *Troy Co. v. Products Research Co.*, 339 F.2d 364, 367 (9th Cir. 1964), cert. Dismissed, 381 U.S. 930 (1965). The Vandenberg court further stated “this would be particularly true where the copyist had itself attempted for a substantial length of time to design a similar device, and had failed”) *Id.*

Thus from the above, it is clear that evidence indicating failures of others to produce a solution is **not essential** to validate evidence of copying and **does not de-facto detract** from such evidence (either considering that a company’s efforts would not be public or considering that such company did not, in fact, invent the product). Rather, it is merely supplemental to such evidence of copying. Proper consideration of the evidence of copying by the Board is respectfully requested.

(E) The Examiner did not recognize that the weight of the secondary consideration evidence obviated the proposed prima facie cases of obviousness.

In the December 18, 2006 office action, the Examiner laid out a lengthy rebuttal of all of the secondary consideration categories presented by the Applicant, including the evidence of commercial success, the evidence of copying by others, and the evidence of long felt need provided by the various declarations of Mr. Leon Hirsch (the contents of which are incorporated by reference).

Subsequent to the last office interview, we consulted the independent experts, Dr. Berlin and Dr. Glaser, in order to get an understanding of: 1) whether experts in Audiology would consider the Vivatone product to be successful; 2) whether experts in Audiology would consider Oticon, Hansaton, Interton, Siemens and Phonak to have copied Vivatone (rather than copying Feeley or Pluvinage designs); and 3) whether Vivatone really satisfied a long felt need in the industry (i.e., how did experts view the introduction of the Vivatone product (as just another product, or really a new category

solving all sorts of needs in the art)). The declarations of Drs. Berlin and Glaser are also incorporated by reference.

Even a brief review of each of these experts Curriculum Vitae show that these two independent experts are in the top of their profession. Each of these experts comment both on the prior art rejections, and substantiate the viability of the secondary consideration evidence, including the evidence of commercial success, long felt need and copying.

As will be discussed in detail below, each independent expert wholly validated the Vivotone product's commercial success; both refuted the Examiner's contention that Feeley or Pluvinage was copied (rather than Vivotone) and positively indicated that Vivotone was copied; and indicated that the Vivotone product was, indeed, a new category, revolutionary, etc., in the hearing aid industry.

The Evidence of Commercial Success

Both Dr. Berlin and Dr. Glaser positively declared that they considered the Vivotone hearing system commercially successful, despite minimal advertising, no name recognition, and market derived bars to entry (i.e., penetration of the market despite things like distributor loyalty to large manufacturers, large advertising campaigns by competitors, etc.).

The Vivotone Hearing Aid Was Revolutionary; A Head Turner

Referring to Dr. Glaser's Declaration, paragraph 16, Dr. Glaser positively indicates a belief that upon introduction, the marketplace regarded the Vivotone product as "a clever design that unequivocally turned heads in the Audiology community." Indeed, Dr. Glaser indicates that Vivotone "has done quite well in the marketplace because of their unique configuration and product presentation (the small BTE component with the microphone port, the thin speaker wire, and the small speaker suspended in the ear canal)." Thus, Dr. Glaser ties Vivotone's commercial success directly to key aspects of Vivotone's open design and positively indicates that the Audiology community saw the Vivotone hearing aid as "clever" and "a head turner."

We note that the Examiner expressed a belief that the Vivotone System was not the type of product that would be a head turner (the “I’ve got to have it” type of product similar to the Ipod). Dr. Glaser’s declaration refutes the Examiner’s claim. Dr. Berlin’s declaration also directly refutes this in paragraph 13, indicating that the Audiology community could *immediately see the unique value of the Vivotone system* (the ability to emergently fit patients without resorting to molds, waiting or readjustment being just one of the advantages).

Dr. Berlin emphatically described the Vivotone product as “*revolutionary*”, indicating that when he first saw the product in 2004, he felt that it would “*change the industry*.” (see paragraph 5 of the Berlin Declaration). Dr. Berlin also indicated that the Vivotone product would “*change the way hearing aids are made and distributed.*” (paragraph 11).

Vivotone’s Commercial Success was Phenomenal; Sales Soared

Dr. Berlin also indicated that Vivotone’s *commercial success was “impressive*, particularly because Vivotone spent very little on advertising and had no broad name recognition in the industry.” He also indicated that “*most small companies fail for those same reasons.*” (See paragraph 11 of Dr. Berlin’s declaration).

Dr. Glaser similarly declared that Vivotone’s *product sales “soared before similar competing products were introduced.”* Dr. Glaser noted that sales soared “*despite* the fact that most Audiologists have *fairly strong ties to certain manufacturer’s product lines* and *despite* the fact that Vivotone did *little direct advertising*” (citing *word of mouth industry buzz* /re Vivotone’s product).

In sum, both experts cite substantial commercial success despite bars to market penetration for small companies (including little advertising, audiologist ties to existing manufacturer’s product lines and lack of name recognition).

Advertising Directly Affects Sales

Both experts also discount the Examiner’s contentions that the hearing aid

industry is not affected by advertising (because advertising in the marketplace does not directly affect sales). Dr. Berlin *directly refutes* this statement in paragraph 12, citing Miracle Ear ads on CNN, and Beltone and Siemen's television advertising schemes. Referring to the Examiner's contentions, Dr. Berlin DIRECTLY states: "**Vivatone's commercial success was driven by word-of-mouth referral and was phenomenal** (despite minimal advertising). **It should not be discounted.**"

Dr. Glaser points to the need and activity of manufacturers in "*marketing their products to audiologists and hearing aid dispensers.*" (see paragraph 16). Dr. Glaser positively states, "**The hearing aid industry is heavily affected by advertising.**" He continues, "**Marketing to professional audiologist as well as the consumers is an extremely expensive proposition within the hearing aid industry. As such, Vivatone's commercial success should be seen as even more remarkable because of the fact that Vivatone's advertising expenditures were so minimal.**"

The Examiner also quoted Alan Dozier from GN Resound, who stated "Not a lot of consumer advertising is being done to build confidence in hearing aid instruments and build brand awareness." Dr. Glaser positively agrees with the statement as it relates to conventional hearing aids, but "*completely disagrees*" as it relates to Vivatone, which is a "*new category of hearing aids.*" (see paragraph 16 of Dr. Glaser's Declaration). Dr. Glaser further states that the Vivatone product "*has spurred a change in the hearing aid industry as it relates to marketing efforts. Indeed a great deal of advertising is now being done for this category (a 'this is not your father's hearing aid' type of response to the Vivatone configuration).*" Dr. Glaser cites the marketing materials of Oticon, Siemens, Hansaton, Interton and Phonak as exemplary.

Dr. Berlin similarly indicates that Alan Dozier's statement *does not relate* to "this new category of hearing aids." Dr. Berlin also cites the advertising of Oticon, Siemens, Hansaton, Interton and Phonak as *directly reflective of industry change resultant from Vivatone's "revolutionary design."*" (see paragraph 14 of Dr. Berlin's Declaration).

The Revolutionary Nature of Vivatone Does Not Allow For Comparison With Conventional Designs (Re Market Data)

Related to Dr. Berlin's and Dr. Glaser's comments immediately above, the Experts do not consider Vivotone's market share to be comparable to other conventional categories of hearing aids, such as BTE-tube designs or BTE designs in general.

Dr. Glaser notes, near the end of paragraph 16, that "*comparison of the open canal Vivotone system* (and the similar Oticon, Hansaton, Siemens, etc. systems) *with conventional BTE tube systems* is...not really effective (it is the '*apples to oranges*' comparison)." Dr. Glaser positively indicated that the Vivotone system was a "*new category of hearing aids*." (see paragraph 16 of Dr. Glaser's Declaration).

Dr. Berlin similarly stated, "Vivotone is *simply not comparable* to other devices..." (paragraph 11). Dr. Berlin also stated, "**the revolutionary nature of the Vivotone system does not allow for comparison with conventional designs (even with "open fit" tube designs, which are a subcategory of the BTE category).**"

Accordingly, Vivotone held the entire market share of this new category, until Oticon, Hansaton, Siemens and others became competitors in this category by copying the Vivotone configuration. The market data of other categories, even "open fit" tube designs, do not relate.

In summary, the independent declarations of Drs. Berlin and Glaser can leave no doubt that the Audiology industry considers Vivotone to have enjoyed **phenomenal** and **un-refutable commercial success** by introducing Vivotone, **which the industry considered revolutionary/ the first in a new category of hearing aids/ a product that changed how the hearing aid industry manufactured, distributed and marketed hearing aids.**

The Evidence of Copying by Others

Drs. Berlin and Glaser Indicate Copying by Oticon, Siemens, etc. Rather than Feeley or Pluvimage

Dr. Berlin declared, at paragraph 5, that he considers Phonak, Siemens, Interton, Oticon and Hansaton to have copied Vivotone's essential configuration. Dr. Berlin does note that, "while various versions of these devices may have different or additional

features, *they have all taken Vivotone's essential design (which design I considered and still consider to be revolutionary)*, including the small BTE with the microphone port, the thin speaker connecting wire, and the small speaker suspended in the ear canal.”

Dr. Glaser also declared, at paragraph 5, that “*since the introduction of the Vivotone hearing aid, other manufacturers have seen fit to produce hearing aids in this category.*” Dr. Glaser indicated (paragraph 9) that these competitors have taken the “principal element” of the Vivotone hearing aid design (despite having produced products with additional electronics, software compression, etc.). With regard to these copies of Vivotone, Dr. Glaser concludes, “**...the basis of their offerings in this new class of hearing aids obviously stems from the Vivotone product.**” In paragraph 16, Dr. Glaser states, “**...it is clear to me that the other major manufacturers of hearing instruments have seen fit to copy the product.**”

Drs. Berlin and Glaser made the above statements after being made aware of the Feeley and Pluvinage teachings. Despite those teachings, as evidenced by the above, they each independently and firmly believe that the essential Vivotone hearing aid system was copied rather than any of the teachings in the prior art. Dr. Berlin further indicates (paragraph 15) “*...devices supposedly patented before Vivotone do not directly address the problems of Occlusion and Insertion loss separately in the creative manner exemplified by Vivotone.*” Dr. Glaser indicates at the end of paragraph 16, “**the Pluvinage instrument also does not compare. The Vivotone system is an advancement in that it rejects the BTE-tube designs as well as the hybridized tube design of Pluvinage.**”

Accordingly, the independent experts *separately reject* the Examiner’s contention *that the competitors copied the prior art* Feeley or Pluvinage teachings, while at the same time *separately confirm* that these *competitors copied the essential aspects of the Vivotone design.*

The Laudatory Statements of Competitors

The Examiner contended that the laudatory statements can be directed not only to the applicant’s invention but to the Pluvinage and Feeley hearing aids. However, *both*

Drs. Berlin and Glaser indicate the advertising of Oticon, Siemens, Hansaton, Interton and Phonak as directly reflective of industry change resultant from the introduction of the Vivotone product. (see Dr. Berlin's Declaration at paragraph 14 and Dr. Glaser's Declaration at paragraph 16). Further, each of the independent experts indicate that these competitors, while they may have varied features, such as additional electronics, software compression etc., **obviously copied the essential or principal aspects of the Vivotone system (not the prior art).** (See Dr. Berlin's Declaration at paragraph 5 and Dr. Glaser's Declaration at paragraph 9). **Accordingly, the laudatory comments relate directly to the essential aspects of the Vivotone device, and not the Feeley or Pluvinage devices.**

The Evidence of Long Felt Need

The Vivotone Hearing Aid Was Revolutionary

Referring to Dr. Glaser's Declaration, paragraph 16, Dr. Glaser positively indicates a belief that upon introduction, the marketplace regarded the Vivotone product as "a clever design that unequivocally turned heads in the Audiology community."

Dr. Berlin's, in paragraph 13, indicated that the Audiology community could **immediately see the unique value of the Vivotone system** (the ability to emergently fit patients without resorting to molds, waiting or readjustment being just one of the advantages). Dr. Berlin emphatically described the Vivotone product as "**revolutionary**", indicating that when he first saw the product in 2004, he felt that it would "**change the industry.**" (see paragraph 5 of the Berlin Declaration). Dr. Berlin also indicated that the Vivotone product would "**change the way hearing aids are made and distributed.**"

The revolutionary nature of the product is reflective of the fact that the Vivotone system satisfied a long felt need. As noted by Dr. Berlin, the traditional, long felt problems of Occlusion and Insertion loss, have been obviated by Vivotone's non-obtunding design (paragraph 15).

Independently, Drs. Berlin and Glaser declared that the Audiology industry considers Vivotone's **commercial success to be phenomenal and un-refutable.** They indicated that **Vivotone pioneered a new, revolutionary category of hearing aids that**

was summarily copied by competitors because of Vivatone's unique essential configuration. Drs. Berlin and Glaser confirmed that both the **copying and laudatory statements originate from Vivatone's unique essential configuration** and not the prior art. Drs. Berlin and Glaser also indicated that the genesis of this copying stems from the **Vivatone hearing aid's unique solution to the long felt problems** of the industry.

As is noted above, proper consideration of the above, substantial secondary consideration evidence must be made. This evidence provides textbook indicia of patentability.

(F) *Claims 1-7, 40, 42-53 and 59-63 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage.*

Of primary point, we note that Pluvinage does not teach the following limitation: “the receiver generating **about three decibels or below of insertion loss** over a portion of the human ear audible frequencies.” The Examiner uses Pluvinage as its sole reference in this regard. More specifically, the Examiner asserts that the term “insertion gain,” as used by Pluvinage in Figure 11 and Col. 8, lines 15-25, is the same thing as the insertion loss described and claimed by the Applicant. The Examiner also indicates that the claims are indefinite in this regard because of “things like non-linear varying unoccluded responses of ears and variability of stimulus.”

As we have noted above, the presently claimed subject matter relates to insertion loss, not insertion gain. Reference is made to Dr. Berlin’s declaration at paragraph 2(j), which teaches the differences between insertion loss and insertion gain. Insertion loss is a measurable value that does not vary according to SPL (this is because it is measured with the hearing instrument turned off). It is absolutely a measurement related solely to size of the hearing aid in the ear (no amplification function, no compression function). Accordingly, the claims are definite.

The Examiner also indicates that the “insertion loss” term is a mechanism of defining structure according to function. This is not so. The Vivatone insertion loss is a characteristic of the open ear Vivatone system, which comprises a small speaker suspended in the ear and connected to the BTE via a thin wire.

With regard to the “about three decibels or below of insertion loss limitation”, reference is made to Dr. Berlin’s Declaration at paragraph 7 and Dr. Glaser’s Declaration at paragraph 11. Therein, the independent experts clearly indicate that Pluvinage does not teach about three dB or below of insertion loss. Pluvinage’s teachings about insertion gain **can have no bearing** on insertion loss. At paragraph 6, Dr. Berlin indicates that the described Pluvinage system, which requires multiple tubes/components side by side in the ear canal, significantly occludes the ear canal relative to the Vivatone configuration (indeed, because of this significant occlusion, it would make sense that this system would generate significant insertion loss).

Dr. Glaser similarly indicates, at paragraph 11, that Pluvinage does not teach three decibels or below of insertion loss or that, in a switched off mode, the side-by-side profile would generate three decibels or below of insertion loss.¹

Because the three decibel or below of insertion loss limitation is not taught or suggested by Pluvinage, a *prima facie* case of obviousness has not been made out. Thus, the Examiner’s rejections are in error.

Further, as noted by Dr. Berlin’s declaration, paragraph 6, removal of the sound sampling tube was not an obvious change at the time of the Pluvinage application. Specifically, Pluvinage **REQUIRED** the microphone tube or microphone in the ear canal *to control feedback and to make its own probe microphone measurements*. Because the proposed modification is improper, the Examiner’s rejections are similarly in error.

Dr. Glaser also noted, at paragraph 13 of his declaration, that an audiologist possessing ordinary skill in the art would not have been motivated to modify the Pluvinage device to achieve the Vivatone hearing aid system. Dr. Glaser also notes that Pluvinage **requires both delivery of and sampling of sound within the ear canal**.

Because the requisite motivation to modify the Pluvinage device is lacking, as independently confirmed by two experts in the field, the Examiner’s rejections are in error.

¹ Dr. Glaser also indicates (even though Pluvinage’s measured insertion gain has no bearing on its insertion loss) that even at 80 dB SPL, for certain frequency ranges, Pluvinage’s insertion gain is shown to be greater than 3dB in Figure 11.

The foregoing also makes sense with regard to Pluvinage's best mode requirement. Pluvinage believes that its multi-component configuration is ideal. Indeed, as noted by Dr. Berlin, Pluvinage *requires* the microphone tube or microphone in the ear canal *to control feedback and to make its own probe microphone measurements.* Pluvinage clearly disclosed its best mode, *which requires the microphone tube or microphone in the ear canal* (indeed, Pluvinage was obligated to).

Pluvinage did not disclose the Vivotone system (if Pluvinage believed such a system was better, it would have and should have disclosed it). Because Pluvinage **REQUIRES** the microphone tube or microphone in the ear canal, and/or because there is no motivation within Pluvinage to remove the sound tube to essentially find the Vivotone system (the prohibition against hindsight reconstruction and using the Applicant's own specification as a roadmap is reiterated), the rejection is improper.

In sum, the Pluvinage system 1) does not teach or suggest the "three decibels or below of insertion loss" limitation; 2) would not work as intended should the microphone tube be removed; and 3) does not provide motivation to make such a change. Further, Dr. Berlin and Dr. Glaser each noted Pluvinage's *requirement* for the sound tube *and the lack of motivation* within Pluvinage or within the art to remove that sound tube.

As to the Examiner's assertion that one skilled in the art would be motivated to remove the sound tube *to avoid infringing the Pluvinage claims*, both Dr. Berlin and Dr. Glaser noted that they would ABSOLUTELY not have known to do this, since they are not patent lawyers. They would not have even been thinking along those lines.

Indeed, as is noted above, the Examiner's assertions would mean that "one of ordinary skill in the art" would necessarily have to be a licensed patent attorney, having the training and ability to perform claim construction of claim terminology based on the specification and the prosecution history in order to understand whether a product that they might dispense would potentially infringe (assuming they even cared). To require "one of ordinary skill in the art" to be a patent lawyer goes completely against the plain language and purpose of looking to the understanding of "one of *ordinary* skill in the *art*"

when assessing motivation to combine references or otherwise modify a teaching. In this case, the “*art*” is Audiology, not patent law. Further “one of *ordinary* skill” in Audiology is not a patent lawyer turned Audiologist, or an Audiologist turned patent lawyer; it is an Audiologist. The Examiner’s rejections are in error.

Reference is made to portions of Dr. Berlin’s declaration *refuting* the Examiner’s contentions that: 1) there is motivation to remove the microphone sampling tube of Pluvinage; and 2) that Pluvinage would work just as well without the microphone sampling tube. The below details the expert testimony that independently confirms how the Examiner’s rejections are in error.

In relevant part, Dr. Berlin identified exactly how the microphone sampling tube is **ESSENTIAL** to Pluvinage. In paragraph 8(a), Dr. Berlin indicates that “***BOTH tubes are required, one to record ambient sound through the resonance peaks of the ear canal and the other to bring sound from the processor (described later as a multiband compressor...) to the speaker or receiver in the ear canal.***”

In paragraph 8(b), Dr. Berlin notes that the purpose of the second tube was *essential* to the device’s multipurposes...*to use the ear’s natural resonances* to shape and color the incoming speech, to use the *microphone in the ear to sense and correct for feedback*, (section 8 lines 27-39 and elsewhere)...and to *receive and compare a plurality of signals* (Column 7 Lines 6-16). All of this speaks to and refutes the Examiner’s contention that the second microphone and/or tube could be removed with no real changes to the device. *In light of Dr. Berlin’s rebuttals, the Examiner’s contention is clearly not supportable.* Accordingly, the rejections based on Pluvinage are in error.

Dr. Berlin goes on to indicate in paragraph 8(c) that in their discussions, the Examiner discounted the contents of the processor as being “unknown”. However, Dr. Berlin noted that it actually was clearly described in the text as a *Wide-dynamic range compressor* (See Columns 6 lines 48 to 67: Column 7 lines 6 –16), which he recognized to be a ReSound™ hearing aid, ubiquitous in the early 90s as the best device available for ordinary sensori-neural loss.

Dr. Berlin notes: “*The adaptations required of the processor were IMPOSSIBLE without the use and presence of the second sound tube. This sound*

tubes creates a servo-system connecting microphone to processor to speaker or receiver and smoothing and/or feedback reducing the entire frequency response.”

This servo-system is a required aspect of the hearing aid system taught by Pluvinage. The Examiner contends that Dr. Berlin is asserting that all ReSound hearing aids from the 90s would require this servo-system. Dr. Berlin is not indicating this. Rather, he indicates that the system taught by Pluvinage relies upon and requires this servo-system, of which the sound tube within the ear canal forms an integral part.

In paragraph 8(e), Dr. Berlin unequivocally states, “**In summary, the device would not work as intended without the second tube.**”

Keeping all of Dr. Berlin’s statements in mind, it is clear that, not only would one of ordinary skill in the art **NOT be motivated** to remove the microphone sound tube, the described hearing aid is **REQUIRES** the microphone sound tube. Thus, there can be no motivation to modify Pluvinage. It is also by virtue of this that *KSR International Co. v. Teleflex Inc. et al.* does not apply. There can be no motivation to remove the sound tube when the teachings require the sound tube. Additionally, a *prima facie* case is not made out because the “3dB or below of insertion loss” limitation is not taught by Pluvinage.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As noted by Dr. Berlin, there is no motivation in Pluvinage to remove the sound tube (By direct contrast, the sound tube is **ESSENTIAL**). Accordingly, the testimony of Dr. Berlin confirms that the Examiner’s rejections are in error.

Dr. Berlin also noted that the hearing aid **would not work as intended** without the second tube. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). As indicated by Dr. Berlin,

removal of the microphone sound sampling tube would render the device unsatisfactory for its intended purpose and/or change the principle of operation of the device. **This is a direct indication that there can be no motivation to modify Pluvinage.** As above, Dr. Berlin confirms that the Examiner's rejections are in error.

The Examiner also noted a belief that removal of the sound tube would be inherent in light of the Pluvinage reference. However, we have noted Dr. Berlin's comments indicating how the microphone sound tube is ESSENTIAL to the Pluvinage hearing aid. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Because the sound tube is ESSENTIAL to Pluvinage, the lack of that sound tube *cannot "necessarily flow"* from the teachings of Pluvinage.

(G) *Claims 8, 26-29, 35-37 and 54-57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the "Knowles product catalog."*

Claims 8, 26-29, 35-37 and 54-57 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog. Specifically, the Examiner notes the EH series receiver with a dimension of 3.55mm, which the Examiner indicates is less than half of the average opening of the ear canal at 10mm. However, this rejection ignores that the Pluvinage system includes not just a receiver, but also a microphone or microphone tube alongside the receiver (which would also likely include a casing around the bare receiver). Ignoring the probable casing, just the receiver and adjacent microphone or microphone tube would provide for a maximum lateral dimension that would exceed 50% of a user's ear canal lateral dimension. (See the Declaration of Dr. Berlin at paragraph 7 and the Declaration of Dr. Glaser at paragraph 12). These rejections are similarly in error.

(H) *Claims 9 and 38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of the Knowles product catalog and further in view of Miller.*

Miller teaches a receiver, which as is noted at Column 2, lines 28-30, is particularly suited for in the canal (ITC) hearing aids, which include the receiver, microphone and amplifier in a mold within the canal. There is no motivation within Miller to suspend this receiver in an open ear configuration within the ear canal, such as is claimed by the Applicants.

The deficiencies of Pluvinage have already been detailed above. This rejection also ignores that the Pluvinage system includes not just a receiver, but also a microphone or microphone tube alongside the receiver (which would also likely include a casing around the bare receiver). Ignoring the probable casing, just the receiver and adjacent microphone or microphone tube would provide for a maximum lateral dimension that would exceed 30%, or indeed, 50% of a user's ear canal lateral dimension. (See the Declaration of Dr. Berlin at paragraph 7 and the Declaration of Dr. Glaser at paragraph 12). These rejections are similarly in error.

(I) Claims 64-67 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Pluvinage in view of Mansgold.

While Mansgold does teach multiple sound programs within a hearing aid, Mansgold does not make up for the deficiencies of Pluvinage, as are detailed above. Because of this, the rejections are similarly in error.

(J) Claim 1 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz and further in view of Pluvinage.

Essentially, the Examiner indicates (reference is made to the Examiner's descriptions of the deficiencies of Feeley at page 14, lines 8-11 of the Examiner's July 6, 2007 action) that Feeley does not teach the Applicant's invention because: 1) Feeley requires a mold; and 2) Feeley does not teach the "three decibel or below of insertion loss" limitation of claim 1. The Examiner then indicates that Fretz teaches that blocking of the ear canal can be undesirable, and that venting of molds may not be sufficient.

The Examiner then makes a mental leap by saying that, based on the teachings of Fretz, it would be obvious to do away with the Feeley mold and suspend a speaker in the

ear canal. **However, Fretz did not teach this.** Fretz's alternative to molds was to route a **sound tube** from a BTE into the ear canal. Sound tube BTEs are known.

Feeley's design is from a different class (BTE plus mold). Feeley taught that the mold should preferably be inserted deep within the ear canal such that it touches the bony portion of the ear canal (thus avoiding the occlusion effect). While Feeley does teach that venting may be used, it does not indicate that removal of the mold would be beneficial or desirable (indeed, Feeley requires the mold).

Feeley does not indicate or suggest a solution better than a deeply inserted mold in the ear canal (vented or not). Fretz does not indicate or suggest a solution better than routing a sound tube from a BTE into the ear canal. There is no motivation to combine these references. It is also by virtue of this that *KSR International Co. v. Teleflex Inc. et al.* does not apply. There can be no motivation to remove the mold of Feeley when the teachings require the mold. Additionally, as is noted above, a *prima facie* case is not made out because the “3dB or below of insertion loss” limitation is not taught by Feeley or Pluvinage.

The Examiner also indicates that the Feeley receiver may be replaced with “any Knowles receiver”, as per teachings in Pluvinage. Even if this were the case, it would still be a Knowles receiver secured within a mold (since Feeley requires a mold).

All of the above is reinforced by the declarations of both independent experts, Dr. Berlin and Dr. Glaser. Each indicates that the proposed modification is unsupported by motivation from the references and the art.

Specifically, Dr. Glaser notes, at paragraph 14, that the Vivatone system is not an obvious modification of the Feeley System nor the system described by Fretz.

Dr. Berlin similarly indicates, at paragraph 8, that Feeley and Fretz are disparate solutions, and that one of ordinary skill in Audiology would **not** be motivated to change the CIC device of Feeley. As stated by Dr. Berlin, “Feeley does not describe suspending a speaker in the open ear in any way, the ear canal is not open, and the term ‘open mold’ merely describes a mold vent.” Feeley is not, “and does not suggest the essential Vivatone configuration.”

In sum, both independent experts positively declared that one of ordinary skill in the art would not be motivated to modify Feeley with the teachings of Fretz (The Figure 11 “insertion gain” teachings of Pluvinage having been addressed above, which is incorporated by reference) to result in the Vivotone configuration. The art does not in the least teach or suggest suspending the receiver of Feeley in any way for an open ear receiver fit. The Examiner’s rejections are in error.

(K) Claims 19, 21-24 and 58 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of “GN Magazine from January 2005” in view of the “ReSound AiR pamphlet from September 2003” in view of the “GN ReSound article from April 2003.”

The ReSound AiR pamphlet does teach a plastic “sport lock” for the traditional BTE sound tube type hearing aid. It does not teach such a retaining member extending from an electrical connector or a receiver in the ear canal. The Examiner acknowledges that neither Feeley nor Fretz teach such a retaining member. As is noted above, Fretz is simply a BTE-sound tube hearing aid. Feeley has no need for such a retaining member because it is a mold, and because it is preferably inserted deep into the ear canal such that it contacts the bony portion of the ear canal. Given the disparate natures of these devices (i.e., mold of Feeley contacting the canal and the BTE-sound tube natures of Fretz and ReSound AiR), there is no motivation to make these changes. The Examiner’s rejections are in error.

(L) Claims 36-38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Feeley in view of Fretz in view of Pluvinage in view of the Knowles product catalog in view of Miller.

As is noted above, regardless of the receiver chosen for Feeley, the result is still another receiver provided in an ear canal mold. The lateral dimension aspects of the claims (which relate to the profile of the claimed receiver suspended in an open ear configuration) are still not met. The Examiner’s rejections are in error.

(M) Claims 10-12 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner rejected claims 10-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner indicates a belief that small receivers could not have been made at the priority date of the present application. As evidence of this, the Examiner cites the Knowles FK series receiver, which has a rectangular cross section with a maximum dimension of 2.73mm (the Examiner indicates a belief that the receiver must be 2.0mm to be enabled). The Examiner relies upon the FK receiver's 1999 manufacture date and believes that because he has not heard of a smaller receiver since then, that such receiver cannot be produced. This ignores the fact that such a receiver could be made, e.g., with a round cross section (the commercial Vivotone has a roughly round cross section). The Examiner's rejections are in error.

(N) Claims 1-12, 19, 21-24, 26-29, 35, 40, 42-55, 58-60, 62, 64 and 66 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

The Examiner initially indicates that claims 1-12, 19, 21-24, 26-29, 35, 40, 42-55, 58-60, 62, 64 and 66 are indefinite with regard to the hearing aid receiver generating about three decibels or below of insertion loss. The Examiner specifically believes that the insertion loss is relative to sound input levels (thus providing non-linear amplification or attenuation of sounds, etc.). As has been noted above, insertion loss is measured with the hearing aid turned off (note, the Examiner is again confusing this with "insertion gain" as described by Pluvinage, Figure 11). Since the hearing aid is turned off, it stands to reason that there is no need for an indication of sound input levels. This rejection is in error.

Indeed, during the last interview with the Examiner, this term was differentiated from the term "insertion gain." The Examiner suggested amendment of paragraph [0037] to specify that the insertion loss, or insertion effect, is the difference between Real Ear

Unoccluded Response and Real Ear Occluded Response. The Examiner also suggested that the inventor, Dr. Bauman, provide a declaration indicating that the specification and the claims relate to insertion loss, as distinguished from insertion gain.

We previously understood that this issue was resolved. Nevertheless, because the Examiner has reiterated this rejection in the final action, we will detail how the specification relates to insertion loss rather than insertion gain:

In the December 18 office action, the Examiner attempted to equate the “insertion loss” as described and claimed by the Applicant with the “insertion gain” described by U.S. Patent No. 5,987,146 to Pluvinage (hereinafter “Pluvinage”), and in particular the insertion gain described by Figure 11.

During the last office action, the Examiner conceded that: 1) the Applicant described and claimed “insertion loss”; and 2) that Pluvinage described “insertion gain.” The Examiner also recognized that insertion loss is always measured with the hearing instrument turned off, whereas insertion gain is always measured with the hearing aid turned on. The Examiner did contend, however, that insertion loss and insertion gain could be equated at high sound pressure levels (SPLs). We disagree; and more importantly, the independent experts disagree.

Reference is made to the Declaration of Dr. Charles Berlin, paragraph 2, for a description of “insertion loss”, “insertion gain”, and the incompatibilities of those distinctly different measurement types. Reference is also made to the Declaration of Dr. Glaser, paragraph 10, for a similar description of insertion loss.

In paragraph 2, (b) and (c), Dr. Berlin first notes how Real Ear Unaided Response (REUR) measurements are performed. This measurement forms the baseline for either “insertion loss” or “insertion gain” measurements.

In paragraph 2, (d), Dr. Berlin indicates that insertion loss is measured with the hearing aid turned off, wherein the absolute value of the difference of the sound measured with the hearing aid in place and the REUR is the insertion loss.²

In paragraph 2, (j), Dr. Berlin indicates that insertion gain must be measured with

² As a sidebar, it is also noted that Dr. Berlin indicates that open or vented molds (as in Feeley) present measurable insertion losses, whereas the Vivatone device presents almost no insertion losses (See paragraph 2, (g) and (i)).

the hearing aid turned on. Dr. Berlin also indicates that insertion gain and insertion loss cannot be considered the same thing (Insertion gain can drop to zero if the amplifier is exerting a compression function, but this does not equate to zero insertion loss).

Insertion gain is an amplification/compression function that bypasses any obstruction in the ear canal caused by the hearing aid. If one were to place a speaker inside a room and feed a microphone source from outside the room, measurement of the sound from that speaker has no bearing on how thick or acoustically transparent the door is. That is, a hearing aid may have zero or near zero insertion gain by virtue of a compression function, but still have substantial insertion loss by virtue of its size in the ear canal. Pluvinage does not teach three decibels or below of insertion loss.

Dr. Glaser also indicates that insertion loss and insertion gain, as used by Pluvinage, are not comparable (see paragraph 11 of Dr. Glaser's declaration).

In sum, the Applicant describes and claims insertion loss and not insertion gain. Further, because of the nature of the two terms, insertion loss and insertion gain are not comparable (this has further relevance with regard to the Pluvinage rejections, discussed below).

The Examiner also indicates that claims 8-12, 36-38, 56, 57, 61, 63, 65 and 67 are all indefinite in that they recite that a maximum lateral dimension of the receiver is less than a certain percent of the maximum lateral dimension of a user's ear canal. However, simply because the maximum lateral dimensions of users ear canals vary does not render the claim indefinite. On a per user basis, such measurement may be readily made. Further, as the Examiner attempts to do, such dimensions (more practically) may be based on averages of users (there is a fairly defined range of ear canal dimensions).

*(O) Even assuming (simply for the sake of argument) that a viable *prima facie* case of obviousness has been made out, the claims are patentable by virtue of the overwhelming evidence of secondary considerations.*

It should be emphasized that the Applicant has pursued two separate lines of arguments with regard to the Examiner's rejections:

(A) The Examiner's attempted prima facie case of obviousness has numerous flaws, as is evident from a review of the above. For example, we have pointed out that Pluvinage completely fails to teach the 3 dB or below insertion loss limitation. We have also described how the dual tube design of Pluvinage is specifically designed to provide a servo-system connecting microphone to processor to speaker or receiver and smoothing and/or feedback reducing the entire frequency response. We have also explained how the requirement for a mold in Feeley renders it incompatible with Fretz, which is a conventional BTE-sound tube device. Due to the evident flaws in the Examiner's attempted prima facie case, the claims should be judged patentable on the merits.

(B) However, even assuming (simply for the sake of argument) that the Examiner put forth a viable prima facie case of obviousness, we have submitted an expansive body of evidence including secondary considerations that are overwhelmingly in support of patentability of the claims.

A. THE FIRST DECLARATION OF LEON HIRSCH

On September 14, 2006, we submitted the declaration of Mr. Leon Hirsch, president of Vivatec Hearing Systems. This declaration provided evidence of commercial success; evidence of copying by competitors; evidence of long felt need in the industry; and evidence comprising laudatory statements by competitors.

WITH REGARD TO THE COMMERCIAL SUCCESS EVIDENCE

As was discussed in the declaration, when the open ear hearing aid system described and claimed was first commercially launched by Vivatec in the first quarter of 2004, Vivatec was a small startup company whose product line consisted solely of the open ear hearing aid product. Vivatec did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivatec did not engage in any television

or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal.

Notwithstanding the lack of name recognition and advertising, Vivotone's open ear hearing aid has achieved a high degree of commercial success. Indeed, as may be seen from the sales charts at Exhibit 2 in the declaration, domestic unit sales and domestic net revenues steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivotone's open ear hearing aid went from no sales to almost eighteen million dollars. Again, those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.

WITH REGARD TO LONG FELT NEED IN THE INDUSTRY

The Declaration of Leon Hirsch also details how, despite the fact that BTE, CIC, ITE and ITC hearing aids have been available for decades, it was only between 2002 and 2004 (that is, between Vivotone's application for patent and introduction of a commercial open ear hearing aid system) with the introduction of the Vivotone's hearing aid system, that a truly open ear hearing aid system shedding all of the disadvantages of the BTE, CIC, ITE and ITC devices was introduced to the industry. Thus, it took decades for the hearing aid industry to create Vivotone's novel open ear hearing aid system innovation.

While the open ear hearing aid system described by Vivotone's claims took decades to create, it is significant that the above types of hearing aids, and indeed, vented CIC units per se, have been known. Thus, despite the fact that vented CIC units were known, no other company in the field of hearing aids were motivated to separate the electronics from the speaker in the ear canal and place the electronics in a behind the ear unit, electrically connected to the open ear receiver, until Vivotone did so. It is reasonable to conclude that on this evidence alone, (that is, the fact that it took many years for a company to incorporate provide such an arrangement as did Vivotone despite the fact that vented CIC units were well known), it would not have been obvious to provide a hearing

aid device with behind the ear electronics connected to an open ear receiver suspended within the ear canal or to modify the teachings the cited art to provide for such open ear configuration.

WITH REGARD TO THE EVIDENCE OF COPYING AND LAUDATORY STATEMENTS MADE BY COMPETITORS IN THEIR ADVERTISING

We also noted in the declaration that, since the release of Vivotone's commercial product, there has been *substantial copying* of Vivotone's open ear configuration by the large, well-known hearing aid companies. Also, these large and well known companies have been *aggressively marketing* (i.e., numerous and overtly pointed comments relating to) *the open ear aspects, which have been copied* from the Vivotone device and that are described in the pending independent claims.

For example, in February, 2006, approximately 25 months after the introduction of the Vivotone's open ear hearing aid system (note that while Vivotone's sales were \$27,000 in the first quarter, over the course of two years, sales amounted to almost eighteen million dollars), a direct competitor of Vivotone introduced the Oticon "Delta" hearing aid, (hereafter referred to as the "Oticon Delta") (See the Oticon stock exchange announcement at Exhibit 3, dated February 1, 2006). Oticon is a large, famous and internationally well known hearing aid manufacturer doing over five hundred million dollars (\$500,000,000) a year generally in hearing aid sales. As described below, the Oticon Delta includes Vivotone's open ear hearing aid invention. Also, the Oticon marketing literature related to the Oticon Delta continually highlights aspects of Vivotone's open ear hearing aid invention as an extremely significant advance in the hearing aid field. More than that, Oticon uses it's marketing literature in conjunction with it's well known name in the hearing aid industry and, despite Vivotone's prior sales, claims to be the "first hearing aid device in a new category – RITE" (or Receiver in the Ear") (See Declaration of Leon Hirsch, Oticon Delta web page captures at Exhibit 4).

Exhibits 3 – 6 from the Declaration of Leon Hirsch provide various announcements, web page captures and product brochures from the Oticon web site, which describe the Oticon Delta hearing aid as newly providing the hearing aid industry

with the next generation of communications solutions in the RITE (Receiver In The Ear) category. The February 1, 2006 Oticon's stock exchange announcement (Exhibit 3) describes the Oticon Delta as consisting "of two units connected by an ultra-thin, almost invisible copper wire." The announcement goes on to state, "This copper wire connects a newly developed speaker placed inside the ear canal with a small, triangular, digital amplifier placed discretely behind the ear." Oticon's announcement also practically mirror's the present application's specification language as well as Vivotone's brochure language when it states, "By moving the electronics parts behind the ear, we have made room for a completely open solution, without compromising the cosmetic and audiological advantages of the in-the-ear hearing aids." As is clear, for example from Exhibit 3, the Oticon Delta is the same open ear hearing aid system as is embodied by the Vivotone open ear hearing aid system, for which a patent was presently applied for more than 35 months prior to the announcement of the Oticon Delta and for which the Vivotone product was commercially available more than 25 months prior to the announcement of Oticon Delta. This is *clear evidence of copying* in the industry, and as will be described below, *clear evidence of laudatory remarks of our novel open ear aspects by competitors that have copied us in the marketplace.*

Specifically referencing the presently pending independent claim 1, which is reproduced in relevant part above, *the marketing literature for Oticon Delta exactly embodies the bulk of the limitations within the claim. Also, our tests of the Oticon Delta have further shown that the Delta meets the limitation requiring about three decibels or below of insertion loss over a portion of human audible frequencies.*

Referring specifically to the Oticon brochure entitled "Delta's Audiology Concept", Exhibit 5, Oticon states, "With Delta's innovative design, we were able to place the microphones and battery behind the ear in an extremely discrete shell-set and place the Receiver In The Ear (RITE)." Referring specifically to the Oticon Delta design description on Oticon's website, Exhibit 6, the behind the ear unit (1) includes the digital amplifier and microphone sampling ports. The BTE unit connects to the speaker (3), which is in the ear canal, via a thin sound wire (2). The receiver (3) is suspended in the ear canal with their open dome, which includes three arms extending radially away from

the speaker toward the ear canal walls (as noted in the Delta Audiology Concept brochure, Exhibit 5, the “open dome used in Delta provides for the same acoustic response as an open ear, thus providing total occlusion relief.”) (note also that the same brochure contrasts the open ear configuration with use of vents in CIC (completely in canal) hearing aids by noting, “...even with a collection vent, the deep insertion of a CIC does not allow for a totally occlusion free fitting...the resulting occlusion is often enough to limit the acceptance of traditional technology for this very particular group.”) ***Based on the foregoing, all of the elements in the independent claims of the above-referenced application are copied by the Oticon Delta device and are lauded by the Oticon Delta marketing literature.*** Since the Vivotone hearing aid was launched in the commercial market more than 2 years prior to the launch of the Oticon Delta, ***it is evident that Oticon Delta copied Vivotone’s open ear hearing aid system innovation.***

Further, it is significant that ***each and every*** mention of the new Oticon Delta includes laudatory statements regarding the benefits of the open ear configuration (that is, a BTE combined with an open ear RITE) thus supporting the nonobviousness of the presently pending claims.

Reference is made to the Declaration of Leon Hirsch, which itemizes just some of Oticon’s numerous laudatory remarks relative to the benefits of the open ear system, including separating the amplifier from the speaker, positioning of the BTE relative to the open ear receiver and using a thin wire to connect the two.

Though it will not be exhaustively reproduced here, the September 14, 2006 Declaration of Leon Hirsch also details how another large competitor, Hansaton, copies and extols the virtues of the claimed open ear hearing aid system.

B. THE SECOND DECLARATION OF LEON HIRSCH

On November 2, 2006, Leon Hirsch provided a second Declaration. This declaration provided evidence that Siemens, which until recently was the largest hearing aid manufacturer in the world (and is now believed to be the second largest), announced the Centra Active, which is what they call a RIC (“Receiver in the Canal”) product.

On October 17, 2006, Siemens Audiologische Technik, GmbH (“Siemens”) announced its own RIC (“Receiver in the Canal”) hearing aid, called the “CENTRA Active”, which is to be released in the beginning of 2007. *See* the Siemens press release at Exhibit 1, attached hereto. Siemens is also a direct competitor of Vivotone and is currently at least the second largest hearing aid manufacturer in the world (our understanding was that until recently, Siemens was the largest). The Declaration also details how the CENTRA Active also copies Vivotone’s open ear hearing aid invention, as well as how and where the Siemens marketing literature related to the CENTRA Active continually and openly highlights Vivotone’s open ear hearing aid invention as a significant advance in the hearing aid field.

C. THE THIRD DECLARATION OF LEON HIRSCH

On November 28, 2006, we submitted a third Declaration from Leon Hirsch, which declaration detailed how a fourth large competitor, Interton Horgerate, GmbH, introduced a new “Receiver in the Ear” (RITE) hearing aid, which hearing aid copied the claims herein. Interton also lauded the revolutionary nature of the open ear hearing aid.

The declaration also informed the Office that Oticon’s Delta hearing aid was selected as an International CES Best of Innovations 2007 Design and Engineering awards winner. Oticon was taught as having a “revolutionary” product in the Delta, indicating that the industry clearly considered the configuration as new and innovative.

D. THE FOURTH DECLARATION OF LEON HIRSCH

On March 15, 2007, we submitted a fourth Declaration from Leon Hirsch, which declaration detailed how a fifth large competitor, Phonak, introduced the microSavia Art CRT (“Canal Receiver Technology”) hearing aid, which hearing aid copied the claims herein. The Declaration provided additional evidence that Vivotone’s configuration is being copied over and over again by Vivotone’s major competitors.

E. THE DECLARATIONS OF DRS. BERLIN AND GLASER

On March 15, 2007, we submitted the declarations of Drs. Berlin and Glaser to provide the Examiner and the record with the analyses and opinions of those skilled in the art concerning both the technical and interpretive aspects of the merit-based claims as well as their insight into the viability of the evidence of secondary considerations.

Their testimony confirms that the *prima facie* case fails. Their testimony also overwhelmingly validates and bolsters the viability of the secondary consideration evidence.

The Applicants have made diligent efforts, both here and in the previous record, to illustrate how the Examiner's *prima facie* case of obviousness is fatally flawed. The Applicants have also provided tremendous evidence of secondary consideration in support of patentability by way of the three consecutive Declarations of Leon Hirsch, and the subsequent Declarations of Drs. Berlin and Glaser. The claims should be judged patentable on either or both accounts.

CLAIMS APPENDIX

1. A hearing aid, comprising:
 - a microphone sampling position located externally of an ear canal of a user;
 - a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;
 - wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit;
 - the receiver generating about three decibels or below of insertion loss over a portion of the human ear audible frequencies.
2. The hearing aid according to claim 1, wherein the receiver generates about two decibels or below of insertion loss over a portion of the human ear audible frequencies.
3. The hearing aid according to claim 2, wherein the receiver generates about one decibels or below of insertion loss over a portion of the human ear audible frequencies.
4. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 2200 Hertz and about 5300 Hertz.
5. The hearing aid according to claim 4, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3000 Hertz and about 5000 Hertz.

6. The hearing aid according to claim 5, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3500 Hertz and about 4500 Hertz.
7. The hearing aid according to claim 1, wherein the receiver is positioned within the bony and/or cartilaginous region of the ear canal of the user.
8. The hearing aid according to claim 1, wherein the receiver has a maximum lateral dimension that is less than half a maximum linear lateral dimension of a user's ear canal.
9. The hearing aid according to claim 8, wherein the receiver has a maximum lateral dimension that is less than thirty percent of half a maximum lateral dimension of a user's ear canal.
10. The hearing aid according to claim 9, wherein the receiver has a maximum lateral dimension that is less than twenty percent of half a maximum lateral dimension of a user's ear canal.
11. The hearing aid according to claim 10, wherein the receiver has a maximum lateral dimension that is less than ten percent of half a maximum lateral dimension of a user's ear canal.
12. The hearing aid according to claim 11, wherein the receiver has a maximum lateral dimension that is less than five percent of half a maximum lateral of a user's ear canal.
19. The hearing aid according to claim 1, wherein the electrical connection comprises an intermediate connecting portion, wherein a retaining member extends from at least one of the intermediate connecting portion and the receiver, and further

wherein the retaining member is configured to engage at least a portion of the concha of a user's ear.

20. The hearing aid according to claim 19, wherein the retaining member is configured such that the receiver has a maximum insertion depth into an ear canal.
21. The hearing aid according to claim 19, wherein the retaining member is configured such that the receiver does not substantially contact any portion of an ear canal when inserted within the ear canal.
22. The hearing aid according to claim 19, wherein the retaining member stabilizes the receiver in the ear canal.
23. The hearing aid according to claim 19, wherein the retaining member prevents movement of the receiver in the ear canal.
24. The hearing aid according to claim 1, wherein the speaker is at least partially enclosed within a casing having first and second end portions, the first end portion communicating with an intermediate connecting portion, the speaker communicating with a port provided at the second end portion of the casing.
25. The hearing aid according to claim 26, wherein the port is at least partially sealed to debris by a membrane or mesh material.
26. The hearing aid according to claim 27, wherein the casing is sealed to debris at the first end portion and along a length of the casing extending from the first end portion to the port.
27. The hearing aid according to claim 26, wherein the port includes a removable cerumen collector.

35. The hearing aid according to claim 1, wherein the electrical connection comprises an intermediate connecting portion including at least two electrical conducting components provided within the intermediate connecting portion, wherein the at least two electrical conducting components are provided within at least two channels at least partially isolated from one another.
36. A hearing aid, comprising:
- a microphone sampling position located externally of an ear canal of a user;
 - a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;
 - wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit;
 - the receiver having a maximum lateral dimension that is less than fifty percent of the maximum lateral dimension of a user's ear canal.
37. The hearing aid according to claim 36, wherein the receiver has a maximum lateral dimension that is less than forty percent of the maximum lateral dimension of a user's ear canal.
38. The hearing aid according to claim 36, wherein the receiver has a maximum lateral dimension that is less than thirty percent of the maximum lateral dimension of a user's ear canal.
39. The hearing aid according to claim 1, comprising:
wherein the electrical connection comprises an intermediate connecting portion,

an electrical conducting component and a stiffening member, provided on or in at least a portion of the intermediate connecting portion.

40. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1000 Hertz and about 2500 Hertz.
41. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1500 Hertz and about 2500 Hertz.
42. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1500 Hertz and about 2000 Hertz.
43. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 1500 Hertz and about 1800 Hertz.
44. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 2000 Hertz and about 3500 Hertz.
45. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 2500 Hertz and about 3000 Hertz.
46. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3000 Hertz and about 4000 Hertz.

47. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3000 Hertz and about 3500 Hertz.
48. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3500 Hertz and about 4000 Hertz.
49. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 3500 Hertz and about 5000 Hertz.
50. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 4000 Hertz and about 4500 Hertz.
51. The hearing aid according to claim 1, wherein the receiver generates about three decibels or below of insertion loss over audible frequencies between about 4500 Hertz and about 5000 Hertz.
52. The hearing aid according to claim 1, wherein the receiver is positioned within the cartilaginous region of the ear canal of the user.
53. The hearing aid according to claim 1, wherein the receiver is suspended within and away from the walls of the ear canal.
54. The hearing aid according to claim 36, wherein the receiver is positioned within the cartilaginous region of the ear canal of the user.

55. The hearing aid according to claim 36, wherein the receiver is suspended within and away from the walls of the ear canal.
56. The hearing aid according to claim 19, wherein the retaining member is a wire.
57. The hearing aid according to claim 40, wherein the stiffening member is a wire.
58. The hearing aid according to claim 1, wherein the hearing loss programming is saved in memory provided in the behind the ear unit.
59. The hearing aid according to claim 36, wherein the hearing loss programming is saved in memory provided in the behind the ear unit.
60. The hearing aid according to claim 1, wherein the hearing loss programming is reprogrammable.
61. The hearing aid according to claim 36, wherein the hearing loss programming is reprogrammable.
62. The hearing aid according to claim 1, wherein a plurality of hearing loss programs are provided in the behind the ear unit.
63. The hearing aid according to claim 36, wherein a plurality of hearing loss programs are provided in the behind the ear unit.
64. The hearing aid according to claim 64, wherein said plurality of hearing loss programs are selectable by the user.
65. The hearing aid according to claim 65, wherein said plurality of hearing loss programs are selectable by the user.

EVIDENCE APPENDIX

Copies of the following declarations are attached hereto, including the following Declarations:

- A. THE FIRST DECLARATION OF LEON HIRSCH, submitted September 14, 2006.
- B. THE SECOND DECLARATION OF LEON HIRSCH, submitted November 2, 2006.
- C. THE THIRD DECLARATION OF LEON HIRSCH, submitted November 28, 2006.
- D. THE FOURTH DECLARATION OF LEON HIRSCH, submitted March 15, 2007.
- E. THE DECLARATION OF DR. BERLIN, submitted March 15, 2007.
- F. THE DECLARATION OF DR. GLASER, submitted March 15, 2007.
- G. THE DECLARATION OF DR. BAUMAN, submitted March 15, 2007.

RELATED PROCEEDINGS APPENDIX

No opinions have been issued in related application serial number 10/325,529.

CONCLUSION

In view of the foregoing, it is urged that the final rejection of Claims 1-12, 19, 21-24, 26-29, 35-38, 40 and 42-67 be overturned. The final rejection is in error and should be reversed. The fee set forth in 37 CFR 41.20(b)(2) is enclosed herewith. If there are any additional charges with respect to this Appeal Brief, or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

CANTOR COLBURN, LLP

By:


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Date: September 11, 2007



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Leon Hirsch declares and says that:

1. I am President of Vivotone Hearing Systems, LLC ("Vivotone"), and assignee of the above-referenced application. I have been intimately involved in the development, manufacture and sale of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal since 2002.

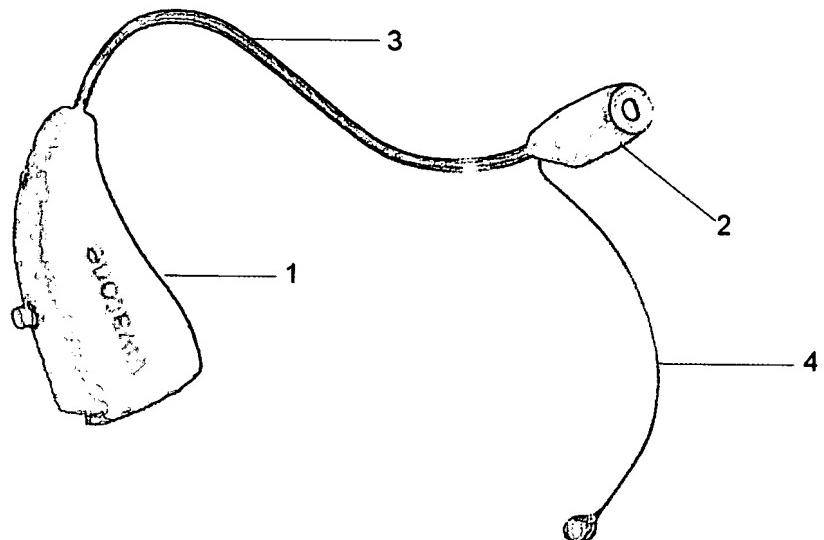
2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:
 - a hearing aid system, comprising:
 - a microphone sampling position located externally of an ear canal of a user,
 - a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal,
 - wherein sound from the microphone sampling position is amplified and passed via electrical connection around a portion of the external ear and through

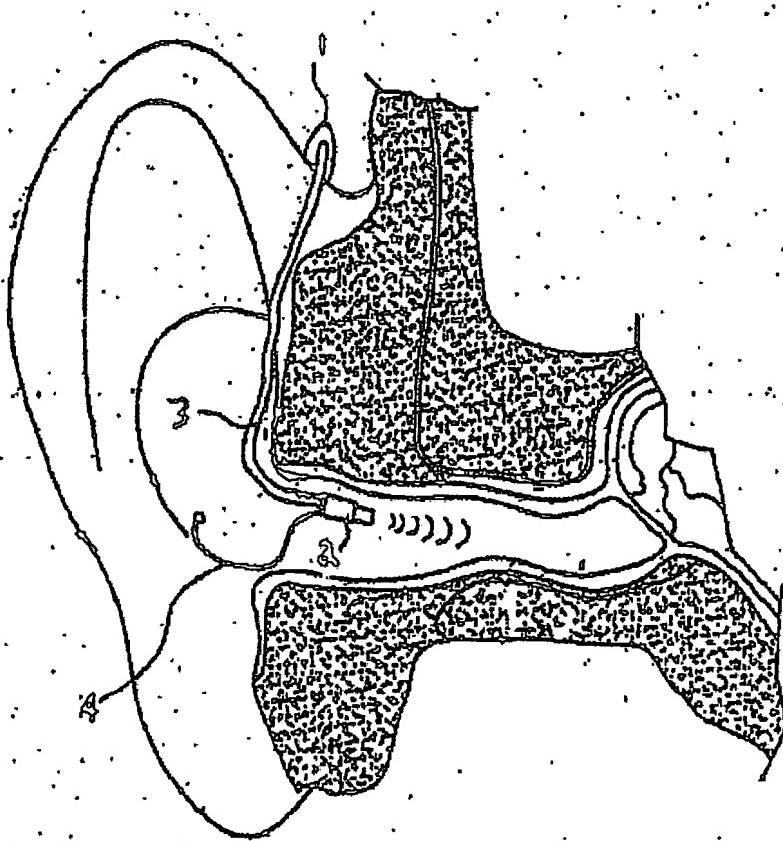
the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration,

wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. The claims of the above-referenced claims correlate with the commercial Vivotone open ear hearing aid system. Reference is made to the following images of the commercial Vivotone device as an aid to review of the following claim chart:





The following claim chart relates aspects of the claimed Vivotone hearing aid to commercialized Vivotone hearing aid to which the above-described commercial success figures above relate. Relevant portions of independent claims (which portions are substantially reproduced in the remaining independent claims) are reproduced below:

A hearing aid, comprising: a microphone sampling position located externally of an ear canal of a user;	The Vivotone hearing aid includes a microphone and microphone port located within the behind-the-ear component (1).
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal;	The receiver (2) comprises a speaker (5) provided within the ear canal in an open ear configuration and is suspended within the ear canal by virtue of the stiffness of the intermediate wire (3) and/or the effect of the concha wire (4).

wherein sound from the microphone sampling position is amplified and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;	The sampled sounds are passed to an amplifier provided in the behind the ear component (1) and are relayed to the speaker (5) via the intermediate wire (3), which is provided around a portion of the external ear into the ear canal opening.
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit	The microphone port and amplifier are both contained within the behind the ear component (1).

The additional aspect of the independent claim 1 is also embodied in the commercial Vivotone device, including the receiver generating about three decibels or below of insertion loss over a portion of human ear audible frequencies.

4. My open ear hearing aid was first commercially launched by Vivotone in the first quarter of 2004, and is embodied in a product designated the "Vivotone Mini", the "Vivotone Standard" or the "Vivotone Dual". At the time of the open ear hearing aid commercial launch, Vivotone, as a small startup company whose product line consisted solely of the open ear hearing aid product, did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivotone did not engage in any television or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal. Notwithstanding the lack of name recognition and advertising, Vivotone's open ear hearing aid has achieved a high degree of commercial success. Sales were generated principally by word of mouth by audiologists, and by side-by-side demonstrations of Vivotone's open ear hearing aid system with other hearing aids. As may be seen from the sales charts at Exhibit 1, domestic unit sales and domestic net revenues have steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more

than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivotone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.

5. Various types of hearing aids have been sold marketed and sold for more than 30 years, including completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately adjacent to the ear canal (e.g., in the bowl of the ear). BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing behind the ear and an open tube for directing sound to the ear canal from the speaker housed in the BTE. The Vivotone open ear hearing aid is the **FIRST** product in those 30 some odd years to incorporate a design that separates the amplification from the speaker, placing the amplification behind the ear (like a BTE device, but unlike the CIC, ITC and ITE devices) while at the same time suspending a small profile speaker in the ear canal to give an open ear configuration. Thus, it took the industry 30 some odd years to create Vivotone's novel open ear hearing aid system configuration, which system minimizes insertion loss and occlusion effect and uses the ear's natural "receiver" to the fullest, mixing natural sounds and amplified sounds in the ear for excellent sound clarity (see the Vivotone Hearing System's brochure at Exhibit 2.

6. While various types of hearing aids have been known for decades, no other company in the hearing aid field was motivated to separate the microphone sampling and amplification from a suspended in-canal speaker (to provide an open ear fitting remote from the BTE microphone and amplifier) until the Vivotone open ear hearing aid in 2004. In my opinion, this fact alone indicates that it was not obvious to provide for such a novel open ear configuration in a hearing aid system.

7. Our open ear hearing aid system resolves the biggest problems that hearing aid wearers experienced prior to the introduction of the Vivotone hearing aid solution:

occlusion, insertion loss, feedback and resonance effects (depending on the type of hearing aid used). Occlusion is the “head in the barrel” effect created when the hearing aid wearer speaks or chews. Feedback is the whistling sound experienced when a patient places a telephone near the ear or other structure. Feedback is similar to the whistling sometimes heard in an auditorium when the microphone is too close to the speaker. Further, BTE devices feeding sound to the ear canal via a sound tube suffer from resonance effects. Vivotone revolutionized hearing aids by developing a product that eliminates the *long felt need* with regard to each of these annoyances. That is, Vivotone enhances hearing while enabling the wearer to enjoy normal speaking, eating or telephone conversation without interference.

8. The reason that Vivotone hearing aids are able to provide these benefits is its unique design. Vivotone’s microphone and amplifier are housed in a small plastic case located behind the ear. Unlike other hearing aids, Vivotone delivers sound from the microphone port in the BTE electronically to its speaker in the open ear canal. The speaker is small enough to allow the ear canal to remain open, and therefore, is non-occluding. This revolutionary approach has advanced the acceptance of hearing aids significantly. As noted, prior to Vivotone, hearing aids either occluded the ear canal or transmitted sound from a speaker located behind the ear to the ear canal through a plastic tube. These designs cause either occlusion or insertion loss or distortion or lack of clarity. Vivotone’s open ear speaker allows the patient’s residual natural sound to combine with the enhanced hearing provided by Vivotone’s processor, giving crisp, clear sound to the patient.

9. In February, 2006, approximately 25 months after the introduction of the Vivotone’s open ear hearing aid system (note that Vivotone’s sales were up to \$17,900,000 from its \$27,000 first quarter sales just two years earlier), a direct competitor of Vivotone introduced the Oticon “Delta” hearing aid, (hereafter referred to as the “Oticon Delta”) (See the Oticon stock exchange announcement at Exhibit 3, dated February 1, 2006). Oticon is a large, famous and internationally well-known hearing aid manufacturer doing over five hundred million dollars (\$500,000,000) a year generally in

hearing aid sales. As described below, the Oticon Delta includes our open ear hearing aid invention; and the Oticon marketing literature related to the Oticon Delta continually highlights our open ear hearing aid invention as a significant advance in the hearing aid field. More than that, Oticon uses it's marketing literature in conjunction with it's well known name in the hearing aid industry and, despite Vivotone's prior sales, claims to be the "first hearing aid device in a new category – RITE" (or Receiver in the Ear") (See Oticon Delta web page captures at Exhibit 4).

10. Exhibits 3 – 6 provide various announcements, web page captures and product brochures from the Oticon web site, which describe the Oticon Delta hearing aid as newly providing the hearing aid industry with the next generation of communications solutions in the RITE (Receiver In The Ear) category. The February 1, 2006 stock exchange announcement (Exhibit 3) describes the Oticon Delta as consisting "of two units connected by an ultra-thin, almost invisible copper wire." The announcement goes on to state, "This copper wire connects a newly developed speaker placed inside the ear canal with a small, triangular, digital amplifier placed discretely behind the ear." The announcement also practically mirror's our 2002 patent application language as well as our brochure language when it states, "By moving the electronics parts behind the ear, we have made room for a completely open solution, without compromising the cosmetic and audiological advantages of the in-the-ear hearing aids." As is clear, for example from Exhibit 3, the Oticon Delta is the same open ear hearing aid system as is embodied by the Vivotone open ear hearing aid system, for which a patent was applied for more than 34 months prior to the announcement of the Oticon Delta and for which the Vivotone product was commercially available more than 25 months prior to the announcement of Oticon Delta. This is clear evidence of copying in the industry, and as will be described below, clear evidence of laudatory remarks of our novel open ear aspects by competitors that have copied us in the marketplace.

11. Specifically referencing our independent claims, relevant portions of which are reproduced above, the marketing literature for Oticon Delta exactly embodies the bulk of the limitations within the claim. Referring specifically to the Oticon brochure entitled

“Delta’s Audiology Concept”, Exhibit 5, Oticon states, “With Delta’s innovative design, we were able to place the microphones and battery behind the ear in an extremely discrete shell-set and place the Receiver In The Ear (RITE).” Referring specifically to the Oticon Delta design description on Oticon’s website, Exhibit 6, the behind the ear unit (1) includes the digital amplifier and microphone sampling ports. The BTE unit connects to the speaker (3), which is in the ear canal, via a thin sound wire (2). The receiver (3) is suspended in the ear canal with their open dome, which includes three arms extending radially away from the speaker toward the ear canal walls (as noted in the Delta Audiology Concept brochure, Exhibit 5, the “open dome used in Delta provides for the same acoustic response as an open ear, thus providing total occlusion relief.”) (note also that the same brochure contrasts the open ear configuration with use of vents in CIC (completely in canal) hearing aids by noting, “...even with a collection vent, the deep insertion of a CIC does not allow for a totally occlusion free fitting...the resulting occlusion is often enough to limit the acceptance of traditional technology for this very particular group.”) (additionally, Oticon’s literature in the same Exhibit also indicates that the open ear receiver solves another long felt need related to use of BTE devices utilizing sound tubing to pipe amplified sound into the ear canal, “...the receiver has been placed in the ear canal where tube resonances and other sound quality limitations of traditional tubing are not a factor.”).

Our tests of the Oticon Delta have further shown that the Delta meets the limitation requiring about three decibels or less of insertion loss over a portion of human audible frequencies.

Based on the foregoing, in my opinion, all of the elements in the independent claims of the above-referenced application are found in the Oticon Delta device and are lauded by the Oticon Delta marketing literature. Since our Vivotone hearing aid was launched in the commercial market more than 2 years prior to the launch of the Oticon Delta, I believe that the Oticon Delta copied our open ear hearing aid system innovation.

12. In addition to my belief that Oticon copied our open ear hearing aid system innovation, it is significant that each and every mention of the new Oticon Delta includes laudatory statements regarding the benefits of the open ear configuration (that is, a BTE

combined with an open ear RITE) thus supporting my contention (by using the competitor's own language) in Paragraph 5 that the open ear hearing aid system innovation is nonobvious. I have yellow highlighted such laudatory statements in each of Exhibits 3 - 6 which state, for example:

<u>Exhibit</u>	<u>Statement</u>
3	“... belongs to a new generation of communication solutions in the RITE (Receiver-In-The-Ear) category”
4	“Delta is the first hearing device in a new category - RITE”
5 p.4	“... takes full advantage of...a totally open fitting” “Unique to the Delta design, the receiver is placed in the ear canal...” “...placing the receiver in the ear canal removes the need to compensate for the resonances created by the sound tubing...” “Clearly, the best solution is to bypass the need for compensation and corrections and to place the receiver in the ear canal...” “...the optimum solution is to implement a unique way of providing sound to the ear canal...One that combines the occlusion free properties of a BTE with the sound quality and cosmetic benefits of a CIC...” “With Delta’s innovative design, we were able to place the microphones and battery behind the ear in an extremely discrete shell-set and place the Receiver In The Ear (RITE style).” “...same acoustic response as an open ear, thus providing total occlusion relief...”
p.10	“To ensure that occlusion is never an issue, Delta provides a totally open fitting concept, allowing the balanced mix of natural and amplified sound.” “...the receiver has been placed in the ear canal where tube resonances and other sound quality limitations of traditional tubing are not a factor.”
6	“...placed in the ear canal to offer unmatched performance and comfort...”

13. As is clear from my description in Paragraphs 8 - 11 above, Oticon has repeatedly and continuously designated the open ear hearing system as a “New” and important feature and as a significant advance in the field of hearing aids. These laudatory

statements exist despite the fact that various different types of hearing aids, including BTE, CIC, ITE and ITC hearing aids, have been known for decades prior to introduction of the Vivotone open ear hearing aid system.

14. Another direct competitor of Vivotone, Hansaton, has recently announced a new hearing aid, “Free Soundmanager”, (hereafter referred to as the “Hansaton Free”) (See the Hansaton web page snapshots at Exhibit 7). Hansaton is another large, famous and internationally well-known hearing aid manufacturer. As described below, we believe that the Hansaton Free also copies our open ear hearing aid invention; and the Hansaton marketing literature related to the Hansaton Free continually and openly highlights our open ear hearing aid invention as a significant advance in the hearing aid field. More than that, Hansaton uses its marketing literature in conjunction with it’s well known name in the hearing aid industry for it’s open ear “Hansaton Free” hearing aid.

15. Exhibits 7 – 9 provide various announcements, web page captures and product brochures from the Hansaton web site. Hansaton’s March, 2006 press release, Exhibit 7, page 1, describes the consumer interest in the idea of Hansaton’s open ear hearing aid system (corresponding to Vivotone’s claimed invention) as follows: “Free VC Open: Delivery has started, the interest and demand from all our customers side is enormous, as well as our backlog of booked orders! We expect to have full ability of supply by mid of April.” Exhibit 8, page 1 describes their “Free Soundmanager Natural” as follows:

Experience the future superlative sound with the innovative natural technology.
The receiver placed directly in the auditory canal with its almost invisible link
enables excellent hearing enjoyment.

Page 2 of Exhibit 8 begins with a large font “OPEN” and follows with the statement, “Open design and maximum wearing comfort – the trademarks of FREE SOUNDMANAGER.” The web page goes on to state:

The “open” design of both versions offers you an extremely pleasant wearing comfort and a very natural sound. That’s what makes the FREE SOUNDMANAGER stand out from normal hearing systems. It’s new design cuts out unpleasant closure effects...

Page 7 of the Hansaton Free hearing aid brochure, Exhibit 9, states that their hearing aid is the “only instrument to combine two benefits...provid[ing] top-of-the-range audiological performance and remain[ing] virtually invisible in the process.” Page 9 at Exhibit 8 reiterates in bolded letters, “Open shape and maximum wearing comfort are the trademarks of FREE SOUNDMANAGER.” Pages 18-19 at Exhibit 9 again emphasize the “Open” and “External receiver concepts” in large font headings.

As is clear from the images of Hansaton Free and from the lauded language in its marketing (e.g., “open” and “external receiver”), the Hansaton Free is very similar to both the Oticon Delta and our Vivotone hearing aids (particularly with regard to a behind the ear unit houses an amplifier and a microphone and is connected via an electrical wire to an open ear speaker suspended within the ear canal).

We have not tested the Hansaton Free; however, review of the images of the device reveal that the device is remarkably similar to both the Oticon Delta and the Vivotone hearing aids. Accordingly, due to the apparent similarities of the Hansaton Free with the Oticon Delta and the Vivotone hearing aids, we expect that the properties of the device will be similar.

Accordingly, we expect that the Hansaton Free is embodied by independent claim 1 of the Vivotone open ear hearing aid system for which a patent was applied for more than three years prior to the announcement of the Hansaton Free and for which the Vivotone product was commercially available more than two years prior to the announcement of Hansaton Free. We believe this to be clear evidence of copying in the industry, and as will be described below, clear evidence of laudatory remarks of our novel open ear aspects by competitors that have copied us in the marketplace.

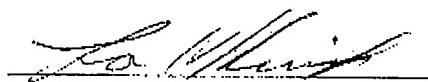
16. In addition to my belief that Hansaton copied our open ear hearing aid system innovation, it is significant that each and every mention of the new Hansaton Free

includes laudatory statements regarding the benefits of the open ear configuration (that is, a BTE combined with an open ear receiver) thus supporting my contention in Paragraph 13 that the open ear hearing aid system innovation is nonobvious. I have yellow highlighted such laudatory statements in each of Exhibits 7 - 9 which state, for example:

<u>Exhibit</u>	<u>Statement</u>
7	<p>“Free VC Open: Delivery has started, the interest and demand from all our customers side is enormous, as well as our backlog of booked orders! We expect to have full ability of supply by mid of April.”</p>
8 p.1	<p>“Free.” (large font)</p> <p>“Experience the future superlative sound with the innovative natural technology.”</p> <p>“...receiver placed directly in the ear canal with its almost invisible link...”</p>
8 p.2	<p>“Open.” (large font)</p> <p>“Open design and maximum wearing comfort – the trademarks of the FREE SOUNDMANAGER.”</p> <p>“The “open” design...offers you...a very natural sound”</p>
9 p.1	<p>“...feel free” (large font)</p>
9 p.3	<p>“Airy. Open.” (large font)</p>
9 p.7	<p>“...only instrument to combine two benefits...top of the range audiological performance...virtually invisible...”</p>
9 p.9	<p>“FREE SOUNDMANAGER – anything but ordinary” (large font)</p> <p>“Open shape and maximum wearing comfort are the trademarks of the FREE SOUNDMANAGER” (large font)</p> <p>“Its new design means that unpleasant occlusion effects and pressure points do not occur at all.”</p>
9 p.14	<p>“Airy.” (large font)</p>
9 p.18	<p>“Open”</p>
9 p.19	<p>“External receiver concept”</p> <p>“Open” (large font)</p> <p>“...does not have the negative effects of an occluded ear as classic systems do.”</p> <p>“External receiver concept” (large font)</p> <p>“As the auditory canal is not blocked with the external receiver, a natural, balanced tone results.”</p>

17. As is clear from my description in Paragraphs 13-15 above, Hansaton has repeatedly and continuously designated the open ear hearing system as a "New" and important feature and as a significant advance in the field of hearing aids. These laudatory statements exist despite the fact that various different types of hearing aids, including BTE, CIC, ITC and ITC hearing aids, have been known for decades prior to introduction of the Vivatone open ear hearing aid system.

I declare under penalty of perjury that the foregoing is true and correct.


Leon Hirsch

September 13, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

EXHIBITS FOR DECLARATION UNDER 37 CFR 1.132

Sir:

Please find the attached Exhibits for the 37 C.F.R. 1.132 Declaration of Leon Hirsch, dated September 13, 2006 and filed on the same day as said declaration.

EXHIBIT TABLE OF CONTENTS

The attached Exhibit includes the following:

EXHIBIT 1: Vivatone Sales charts indicating domestic unit sales and domestic net revenues;

EXHIBIT 2: Vivatone Hearing System's brochure;

EXHIBIT 3: Oticon stock exchange announcement dated February 1, 2006;

EXHIBIT 4: Oticon Delta web page captures;

EXHIBIT 5: Oticon brochure entitled "Delta's Audiology Concept";

EXHIBIT 6: Oticon Delta design description on Oticon's website;

EXHIBIT 7: Hansaton's March, 2006 press release;

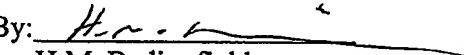
EXHIBIT 8: Hansaton web page snapshot; and

EXHIBIT 9: Hansaton Free hearing aid brochure.

If there are any charges with respect to this submission or otherwise, please charge them to Deposit Account 06-1130, maintained by the Applicant's attorneys.

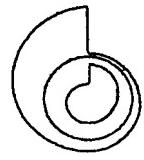
Respectfully submitted,

CANTOR COLBURN LLP

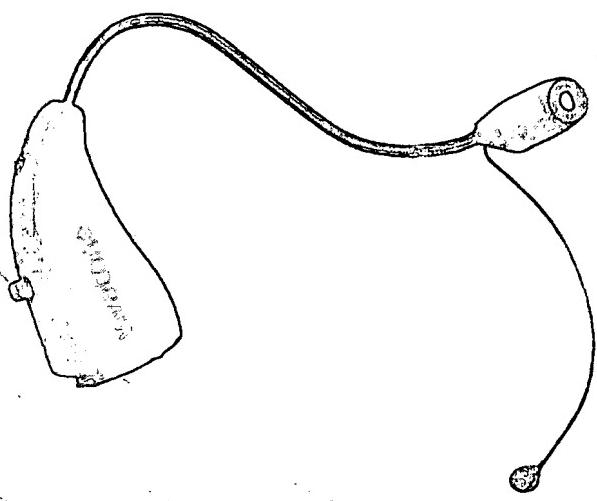
By: 
H.M. Bedingfield
Registration No. 44,530
CANTOR COLBURN LLP
55 Griffin Road South
Bloomfield, CT 06002
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No. 23413

September 14, 2006

EXHIBIT 1



VivatoneTM
HEARING SYSTEMS



Simply Sounds Better

ENTRÉ™ THE NEXT GENERATION OF RECEIVER-IN-THE-EAR TECHNOLOGY WITH FIVE MODELS TO CHOOSE FROM

Enhanced Fitting Range

- New advanced digital processor provides enhanced fitting range, (from 50dB to 70dB between 500Hz to 1000Hz and from 80dB to 90dB between 2000Hz to 4000Hz.)

Five Models Offer the Flexibility You Need

- Multi-channel WDRC Compression Limiting AGC-O
- Up to 12 bands for fine tuning
- Up to 4 memories with programmable memory tone

New Generation Noise Reduction

- Dynamic noise reduction system provides exceptional understanding of speech in any situation. Sophisticated multi-modal detection system analyzes frequency, intensity and temporal characteristics to quickly and effectively differentiate desired sounds such as speech and music from background noise. This provides better speech perception, particularly in noisy situations.

Pre-Amplified Fully Programmable T-Coil

- Optimizes performance when using telephone

Automatic Directional Dual Microphone System

Directional, multi-microphone system with selectable polar plots automatically switches between omni and fixed directional patterns making it easier for patients to appreciate the benefits of directional microphone technology. Choose from three different polar patterns to customize listening programs based on your patient's needs. With the perfect blend of TOC technology, advanced circuitry and cosmetic appeal, it is easy to see why Vivatone is The Leader in Open Ear Technology.

Adaptive automatic feedback cancellation processor

Proprietary phase cancellation algorithm continuously monitors frequency response for feedback to ensure successful feedback elimination with desired gain. Unlike similar systems, Advanced Adaptive Feedback identifies and attacks multiple feedback precursors simultaneously without reducing gain and without increasing battery drain. In addition, the "anti-entrainment" algorithm differentiates music and other tonal signals from feedback. This allows for more gain (3-5dB) prior to feedback, extending our fitting range.

Available in beige and gray

PATIENT BENEFITS



HOW DOES VIVATONE TECHNOLOGY BENEFIT MY PATIENTS?

Vivatone Eliminates Occlusion

Unlike ITC, ITE, and CIC* hearing devices, Vivatone architecture leaves the ear canal open. This eliminates the annoying "echo chamber" sensation common to other devices.

Vivatone Minimizes Insertion Loss

Since Vivatone does not fill the ear, insertion loss is minimized, with no corresponding need to boost lower frequencies to compensate.

Vivatone Offers Flexibility

With up to four programmable memory settings and a directional microphone, Vivatone allows patients to create custom hearing profiles for a wide variety of listening environments.

Vivatone Provides Superior Comfort and Cosmetic Appeal

The open canal design eliminates the "plugged up" sensation common to ITC and CIC devices. Lightweight and virtually invisible, Vivatone is also the discreet solution for patients reluctant to wear hearing devices because of any preconceived "stigma."

Vivatone Simply Sounds Better

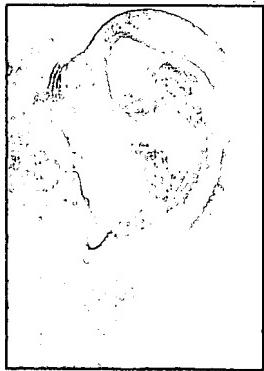
Vivatone mixes natural and amplified sounds in the ear. This combination uses the ear's natural "receiver" to the fullest, resulting in excellent sound clarity.

* In The Canal, In The Ear, and Completely In the Canal

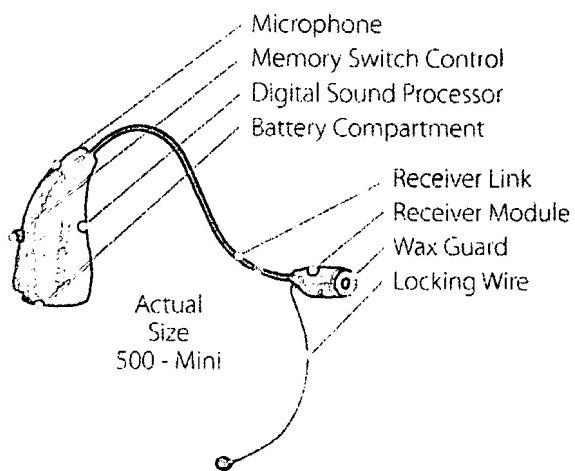
WHAT MAKES VIVATONE™ SO UNIQUE?

ELEGANT SOLUTIONS TO AGE OLD PROBLEMS EXPERIENCED BY HEARING AID WEARERS

The exciting new Entré™ line represents a major advance in digital hearing instruments, offering ultra lightweight design, unmatched cosmetic appeal, comfort and clarity of sound.



Totally Open Canal (TOC) (patent-pending) technology places the receiver directly in the ear canal and places the compact amplifier behind the ear, resulting in unmatched performance, comfort, and aesthetics. By connecting the receiver and the amplifier with a virtually invisible wire, Vivotone hearing instruments eliminate the disadvantage of tubing acoustics and provide crisp, clear sound.



PRACTICE BENEFITS

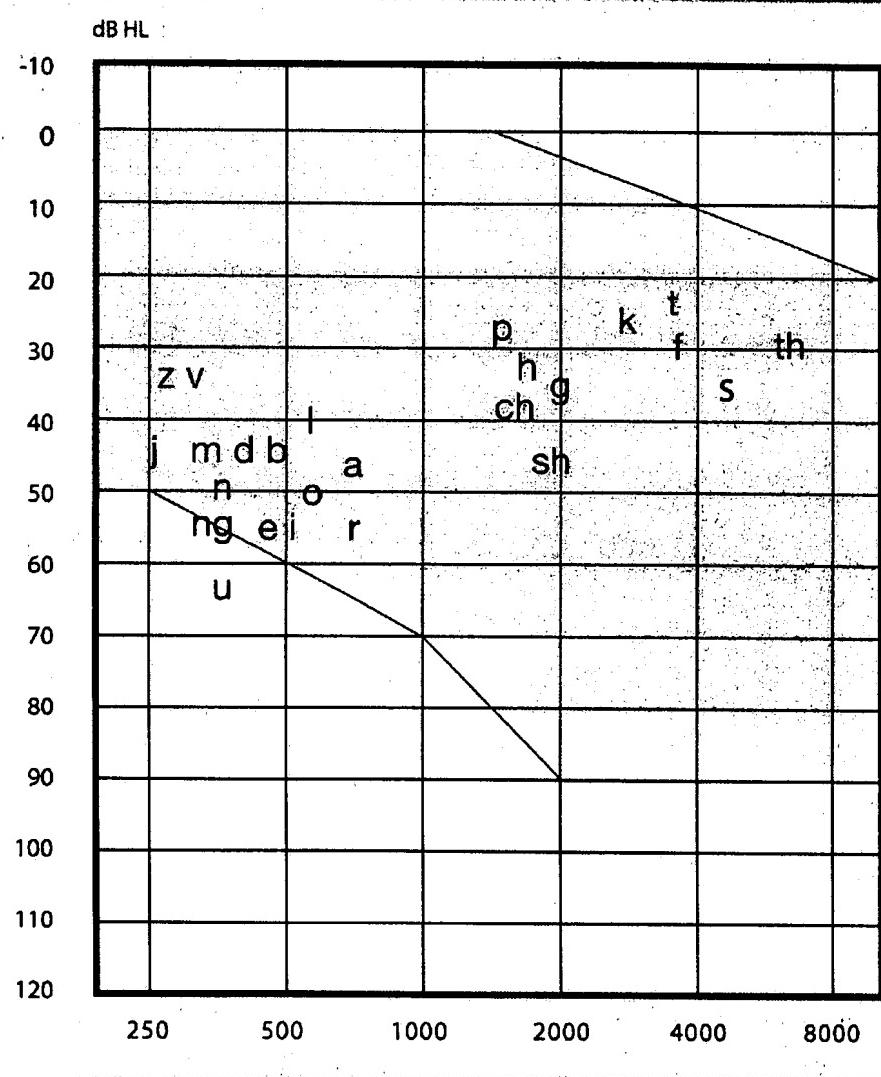


HOW DOES VIVATONE TECHNOLOGY BENEFIT MY PATIENTS?

- **Vivotone Features Easy, Instant Fitting**
Simple-to-fit Vivotone devices are virtually "ready to wear." Your patients enjoy instant gratification and you never have to say "trust me, it's going to sound great" again!
- **Vivotone Eliminates the Need for Ear Molds and Impressions**
Vivotone TOC architecture does not require the costly, time-consuming creation of ear molds or impressions. Vivotone speeds and simplifies fitting while reducing the window of time where patients might "second guess" their investment.
- **Practice Enhancement...**
Vivotone Partners with our Customers
Vivotone works closely with its customers to help grow their practice. The company will customize marketing programs to your needs and location. Vivotone looks at its customers as partners and will provide significant funding for marketing promotions, and supply professional expertise in the preparation and implementation of innovative programs for you.
- **Vivotone Parts Are Replaceable in Office**
The advanced, yet simple Vivotone design allows for quick and easy in-office servicing. Keep your patients happy by providing immediate solutions.

Entré™

Expanded Fitting Range*



Vivatone Hearing Systems, LLC.

One Gorham Island • Westport, CT 06880

www.vivatone.com • 877.278.VIVA (8482)

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Vivatone is a trademark of Vivatone Hearing Systems, LLC.

LB-MKT-204 Rev. 3-27-06

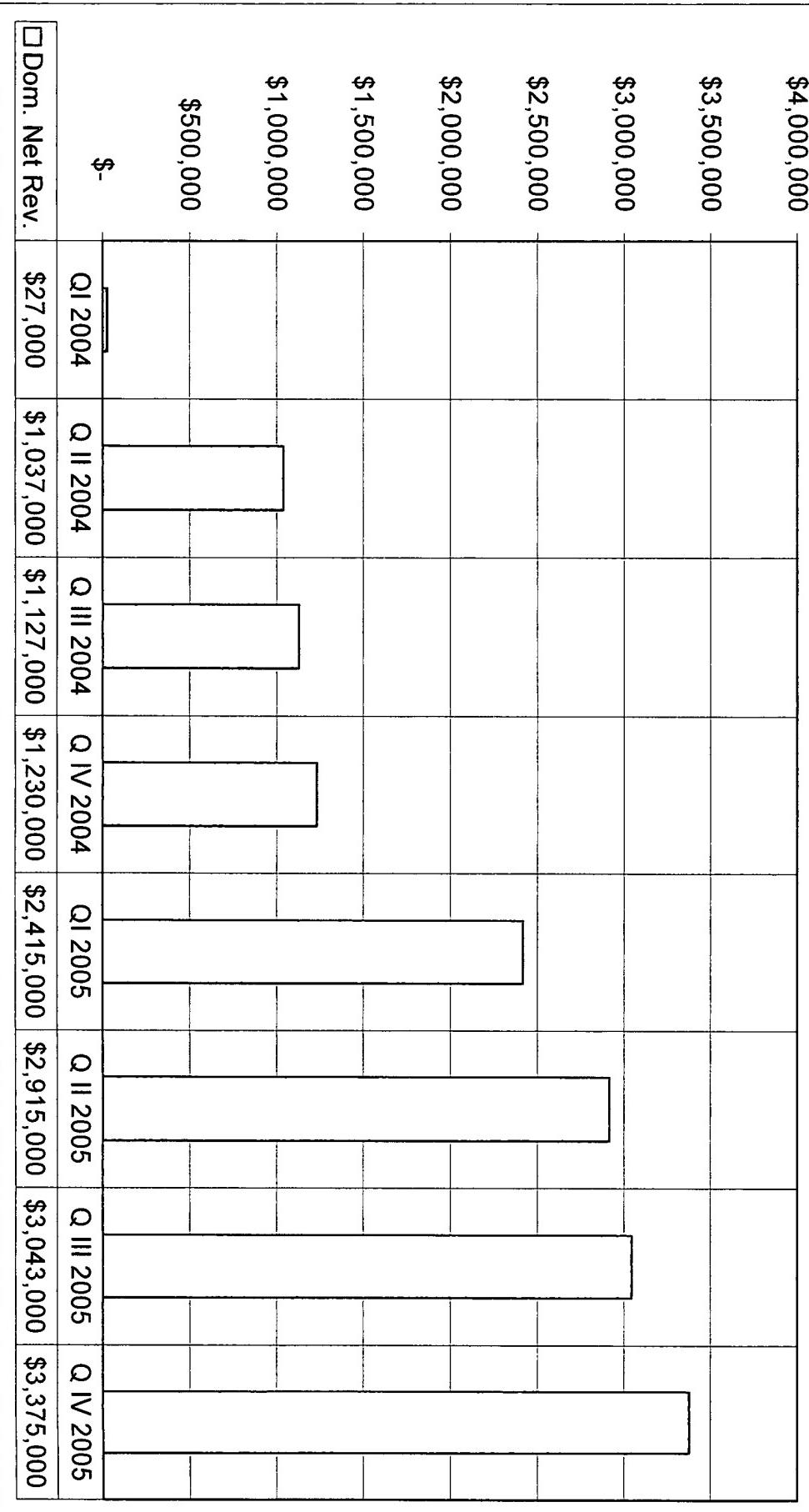
*Representative of data on file.

EXHIBIT 2

Vivatone Hearing Systems, LLC

Domestic Net Revenues

Inception to Dec. 31, 2005



Vivatone Hearing Systems, LLC
Domestic Net Unit Sales
Inception to Dec. 31, 2005

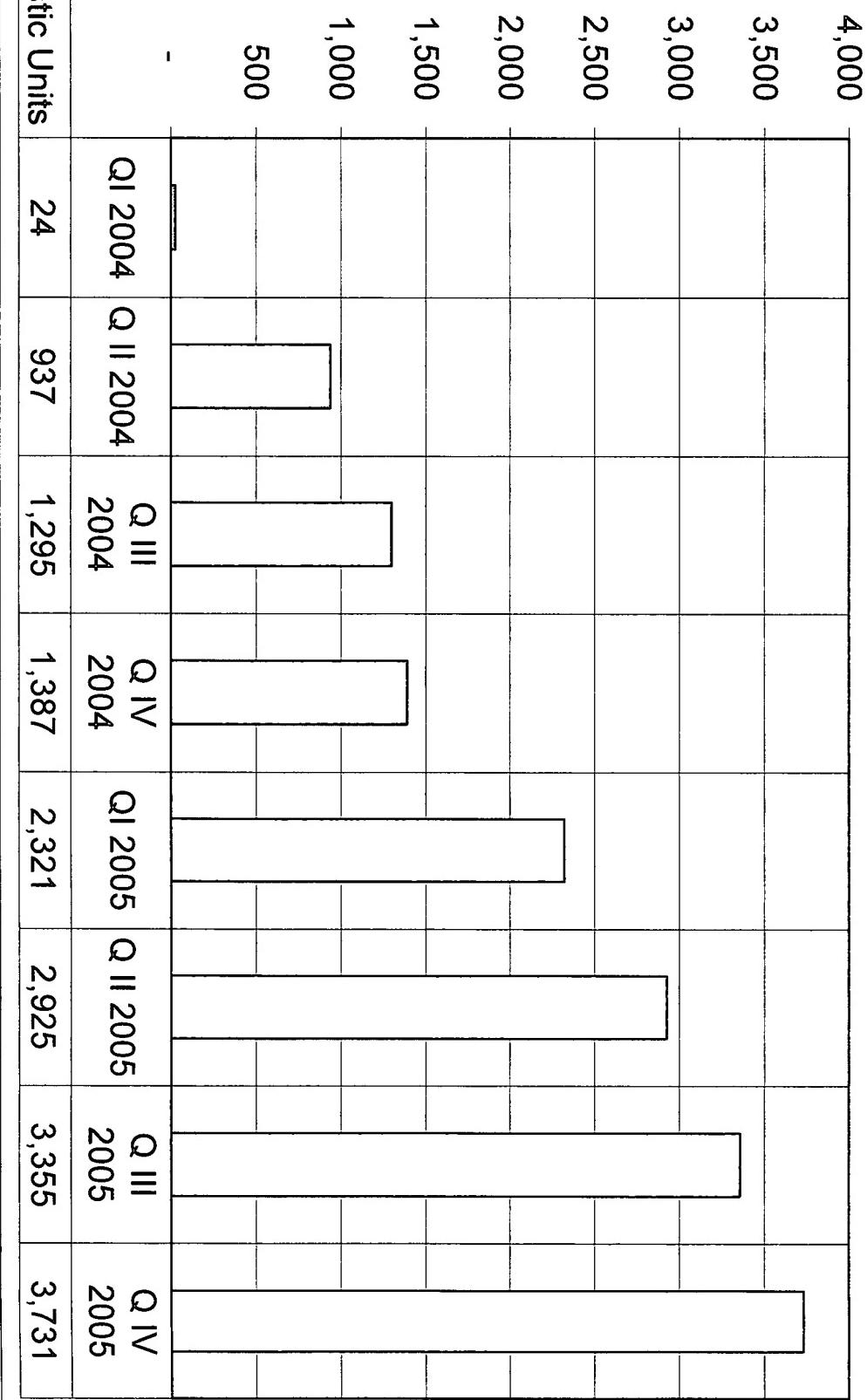


EXHIBIT 3

Stock Exchange Announcement No 2006-01

1 February 2006

Oticon launches new, advanced design product targeted at the "baby boomer" generation

William Demant Holding announces today that the Group's Oticon business is launching a new high-end hearing aid designed to meet the wishes of the fast-growing group of 50 to 65-year-olds – both in terms of functionalities and design. So far, the so-called "baby boomer" generation has been reluctant to use hearing aids.

The new instrument, Oticon Delta, belongs to a new generation of communication solutions in the RITE (Receiver-In-The-Ear) category. Oticon Delta consists of two units connected by an ultra-thin, almost invisible copper wire. This copper wire connects a newly developed speaker placed inside the ear canal with a small, triangular, digital amplifier placed discreetly behind the ear. By moving the electronic parts behind the ear, we have made room for a completely open solution, without compromising the cosmetic and audiological advantages of in-the-ear hearing aids. For example, the potential of the speaker is exploited to the full through its position close to the eardrum. At the same time, the sturdiness and functionality of behind-the-ear hearing aids are maintained.

Oticon Delta contains all the features that characterise the best and most sophisticated products on the market. In the product tests conducted and based on feedback from focus groups consisting of end-users, the impression of Oticon Delta has been very positive. The new Oticon product targets in particular persons with the frequently occurring mild and high-frequency hearing loss. This group accounts for approx. 20-30% of the total market for hearing aids, but accounts for up to half of all first-time users. This target group appreciates state-of-the-art technology and demands elegant design and discretion.

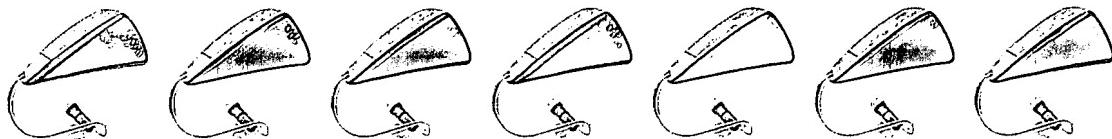
Oticon Delta is expected to be released for sale in March 2006, but already now we are in dialogue with a multitude of dispensers world-wide. At the time of the American hearing aid convention, American Academy of Audiology (AAA), from 5 to 8 April 2006, Oticon Delta will be fully available on all major markets.

"With Oticon Delta, the end-users are offered all available, advanced features together with the most attractive, cosmetic solution on the market. We consider Oticon Delta the most whole-hearted attempt in the business to overcome the younger generations' reservations about the use of hearing aids," says Niels Jacobsen, President & CEO of William Demant Holding.

After the fourth quarter of 2005, the Group maintains its outlook for 2005 in accordance with the most recently expressed expectations. For 2005, the Group thus expects revenues of approx. DKK 4.7 billion and an operating profit (EBIT) of approx. DKK 1.1 billion.

The contents of this announcement do not change the Company's growth expectations for 2006, since at the time of publication of the Company's quarterly review for the third quarter of 2005, Oticon Delta was already included in the plans for 2006. On this occasion, the Company announced that it expects growth in 2006 at least in line with the growth generated in 2005. On publication of the Group's Annual Report 2005 on 6 March 2006, we will elaborate further on the outlook for 2006.

Oticon Delta



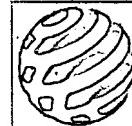
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Contact:

Niels Jacobsen, President & CEO
Phone +45 39 17 71 00
www.demant.com

EXHIBIT 4

- [**< Home**](#)
- [**< Professionals**](#)
- [**< Product information**](#)
- [**□ Delta**](#)
- [**□ Delta generation >**](#)
- [**□ Delta design >**](#)
- [**□ Inside Delta >**](#)
- [**□ Features >**](#)
- [**□ Business tools >**](#)
- [**□ Delta downloads >**](#)
- [**□ Contact us >**](#)



reddot aw
product design

*Delta wins prest
design awai*

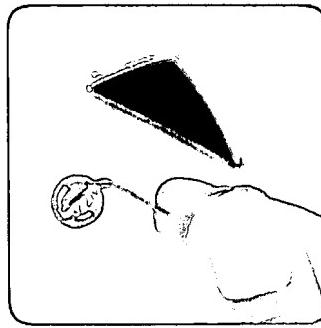
**The promise of change has never been
more of a reality!**

**Introducing Delta - a revolutionary new concept in
hearing devices!**

Featuring the **Receiver In The Ear**, Delta is the first hearing device in a new category - **RITE** - designed to enhance clarity for users with a mild or high-frequency hearing loss. Discreet and cool, Delta houses some of the most advanced technology on the market today!

Nearly 1 of 2 people over the age of 50 have difficulty understanding speech in noisy situations. Finally, you can help more of them to fix their hearing loss. Available in two versions (**Delta 8000 / Delta 6000**). Both solutions feature Delta's groundbreaking design, comfortable sound quality, and superior performance for speech understanding in noise.

[Download Delta brochure \(pdf 480KB\)](#)



Oticon ◊ Delta

[Contact us](#) | [FAQ](#)[Home](#)[Design](#)[Performance](#)[Speech-in-Noise Test](#)[About Clarity loss](#)[Your opinion matters](#)

Nearly one of two people over the age of 50 have difficulty understanding conversation in noisy situations

If you have experienced this, there is no need to worry anymore.

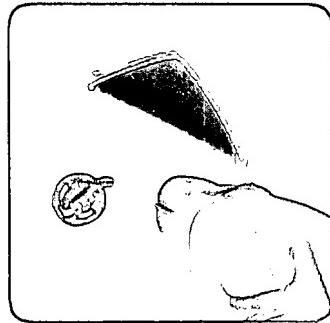
[Country selector](#)[International](#)[France](#)[Germany](#)[Italy](#)

Introducing Delta – a revolutionary new concept in hearing devices that will enhance your powers of communication and ability to connect. To wear Delta will be to join a big club of people who are proud to “own their hearing” – and keep their edge.

[Know more about Delta»](#)

[Take the Speech-in-Noise Test»](#)

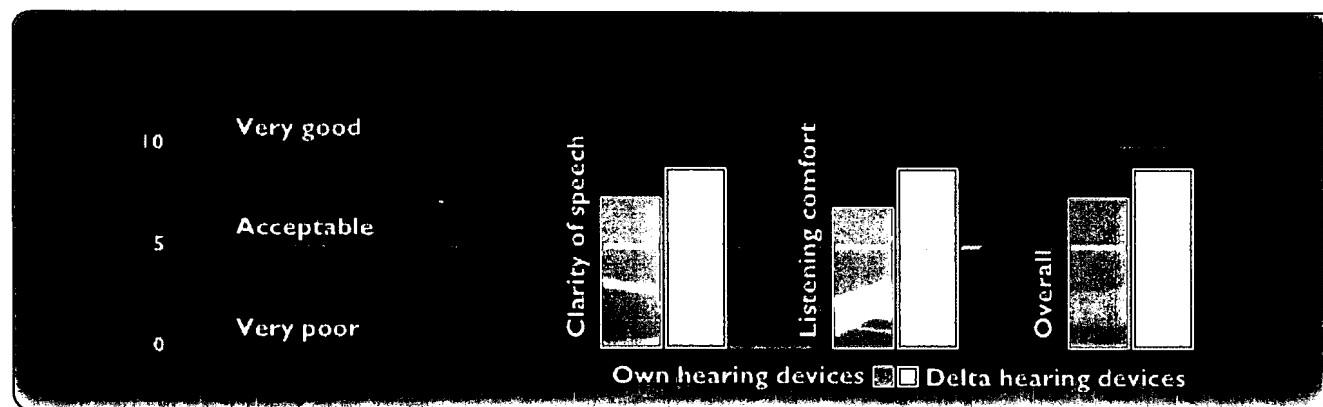
[Delta lounge video \(5MB\)»](#)

[reddot award](#)

**Delta wins prestigious
reddot design award**

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Oticon ◊ Delta

[Home](#) | [Contact us](#) | [Site map](#)
[Home](#)[Design](#)**Performance**[Advanced technology](#)[Superior Sound Quality](#)[Speech-in-Noise Test](#)[About Clarity loss](#)[Your opinion matters](#)**Unmatched performance**

With Delta, you will be totally free to enjoy your new world of understanding without having to think about it. Delta's Artificial Intelligence-enabled system works automatically to deliver the best combination of sound quality, speech understanding and comfort in all situations.

In recent trials, consumers indicated a significant preference for Delta in terms of ease of listening and clarity of speech. Try Delta for yourself and find out how easy it is for you to perform at your best.

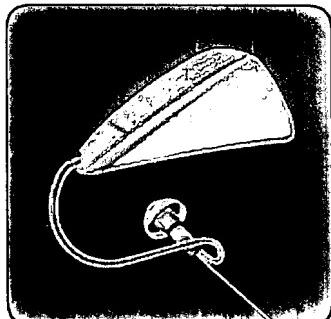
Quotes from consumers trying Deltas:

"Fantastic sound. I never dreamt it could make such a huge difference."

"Speech is very clear. I no longer have to look at people's mouths when they're talking."

"Great to be able to hear more nuances."

"It is easier to participate in discussions at meetings now."

**How to buy Delta**

[Click here to find a hearing center near you](#)

[Hearing care professional](#)

[Tell a friend](#)

[Send a mail](#)

[Home](#) | [Contact us](#) | [FAQ](#)

Almost invisible from any angle

Loading movie 57%

[Home](#)**Design**[Colours](#)**Discreetness**[Shape](#)[Performance](#)[Speech-in-Noise Test](#)[About Clarity loss](#)[Your opinion matters](#)**Virtually invisible**

Delta's unique, triangular shape enables Delta to be as discreet as possible when sitting on your ears.

Connected by a transparent sound wire to a speaker which is placed in your ear canal, Delta is rendered virtually invisible from every angle.

[Look for yourself!](#)**How to buy Delta**

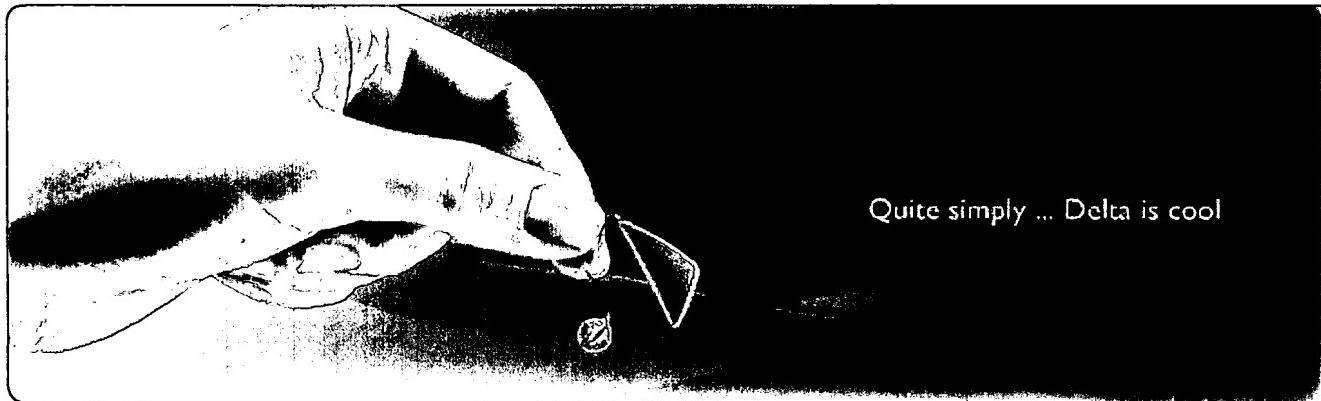
Click here to find a hearing center near you

Hearing care professional**Tell a friend**[Send a mail](#)

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Oticon ◊ Delta

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Quite simply ... Delta is cool

[Home](#)

Design

[Colours](#)

[Discreetness](#)

[Shape](#)

[Performance](#)

[Speech-in-Noise Test](#)

[About Clarity loss](#)

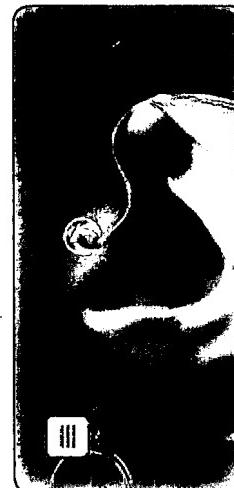
[Your opinion matters](#)

Quite simply... Delta is cool

Designed to sit snuggly behind your ear, Delta's "hi tech" design lets you be completely discreet. Delta blends in beautifully with your skin and hair, but demands attention and admiration in your hand.

With its sporty lines and cool colours, Delta inspires so much confidence that it may well inspire others to follow your lead!

[Range of colours»](#)

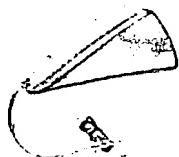


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EXHIBIT 5

Oticon ◊ Delta

Delta Audiology Concept



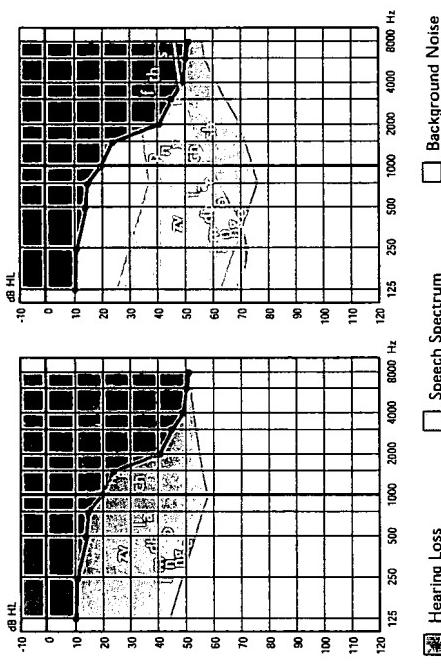


Figure 1: Comparison of the speech understanding potential of people with a mild-to-moderate high frequency hearing loss in quiet versus noise situations. Left panel illustrates that low frequency cues are preserved allowing access to significant cues for speech understanding. Conversely, when communicating in noisy situations (right panel) we see that while people talk louder, the increase in loudness is primarily in the mid frequencies (1000 - 2500 Hz), while high frequency sounds remain inaudible. Unfortunately, background noise masks out the residual low frequency hearing, thus drastically reducing the listener's speech understanding.

1. The focus must be to deliver the best speech understanding in noise. This is contrary to the usual approach for amplification where the aim is to provide improved overall audibility in all situations, and speech understanding in noise being but one situation. The key for this population, is not to solve solely a general audibility issue, but to maximise speech understanding in the most difficult listening situations.
2. This population offers a number of psychological and social challenges. Being younger and more active, they need to preserve their lifestyle and do not wish to have a device that carries with it the perceived stigma of a conventional hearing aid. While sound quality and speech understanding are of paramount importance, aspects such as appearing younger and fashionable are crucial parts of initial acceptance.
3. Excellent sound quality must be delivered for all listening experiences. The user must be able to experience the benefits of amplification without actually noticing the technology. Therefore, all side effects of amplification, such as occlusion, audible transitions between automatic states and compression artefacts (e.g. pumping) must be reduced at all times. This requires a rethinking of the conventional approach to amplification.

is reduced as situations with poor acoustics often co-occur with poor visual cues (e.g. multiple talkers, poor lighting, visual distractions). In these situations, the background noise dominates and masks low frequency speech information, resulting in significant communication challenges. It is for these situations, that amplification focused on restoring high frequency speech cues (e.g. place of articulation) in addition to a general audibility improvement can significantly improve speech understanding in noise³.

Truly meeting the needs of this population requires addressing three key challenges.

Good low frequency hearing leads to near normal speech understanding for many communication situations². These situations are typically one-to-one conversations, where visual cues are abundant and background noise is rare. In noisy situations however, the loss of high frequency information is especially damaging due to the reduction in available speech cues². At the same time availability of visual cues

processing artefacts and audible side effects that may be required to deliver the desired level of performance. Conversely, for people with a high frequency hearing loss, who essentially have a speech in noise problem rather than an audibility deficit, the limiting factor is side effects. They wish to have the maximum speech understanding possible with absolutely no side effects. Therefore, the tolerance level for amplification related issues (e.g. occlusion, sound quality, compression artefacts, tube resonance) is extremely limited and these aspects must be overcome. This means that we must take a totally fresh approach to amplification.

Delta (Figure 2), a new micro hearing instrument offers a solution to meet the specific needs of the user and their demanding listening situations.



Figure 2: The unique design of Oticon Delta allows for both sleek cosmetic design and the ability to provide the optimum microphone spacing and excellent horizontal alignment of the microphones behind the ear.

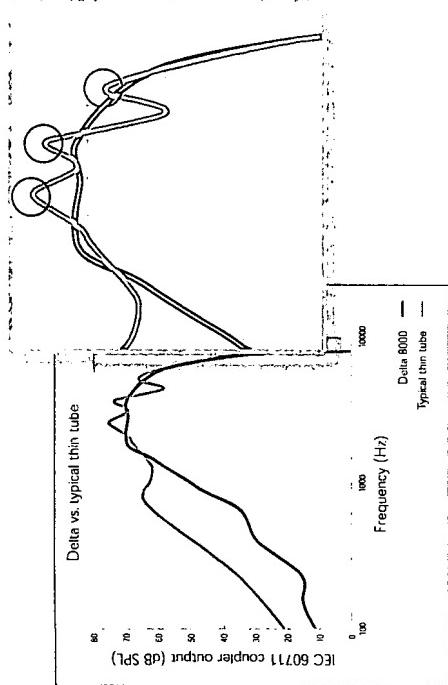


Figure 3: Frequency response from Delta compared with a typical "thin tube" solution showing the improved sound quality by placing the receiver in the ear canal. The typical tube resonance occurring at 2500, 3500 and 4500Hz can be avoided thereby improving sound quality.

results in poorer sound quality. Clearly, the best solution is to bypass the need for compensation and corrections and to place the receiver in the ear canal. A key concept in Delta is to allow the user access to an extended high frequency bandwidth. This is the key to better speech understanding. Figure 4, highlights the speech intelligibility in noise improvement that can be gained from increasing the high frequency bandwidth from 6000 to 8000Hz on a test of consonant identification. It can be seen that 10 of 11 participants showed a significant improvement in access to speech information in a speech reception threshold (SRT) test. Examination of specific speech sounds showed an overall accuracy improvement, but also access to high frequency consonants such as /s/ were improved with an extended high frequency bandwidth. This increased access to high frequency speech energy not only increases speech understanding in

noise but also reduces the degree of perceived listening effort required during the day.

Oclusion Free

The younger population want excellent sound quality in a cosmetically suitable solution. Previously, the primary way to achieve this was with a CIC. Unfortunately, while CIC's provide the desired cosmetics, two problems arise. First, advanced functionality such as directional microphones are not compatible with the deep insertion and small footprint required. Second, even with a collection vent, the deep insertion of a CIC does not allow for a totally occlusion free fitting. The resulting occlusion is often enough to limit the acceptance of traditional technology for this very particular group.

Importantly, the large vent coupled with the significant degree of residual hearing results in a need for less amplification than would be considered if viewing the hearing loss on its own. The totally open vent allows for a

distortion. Placing the receiver in the ear canal removes the need to compensate for the resonances created by the sound tubing (Figure 3). This tube resonance is present whether the tube is a conventional 2mm wide tube or the new "thin tube" style, as it relates to tube length and not width⁴. It is possible in modern fitting software to compensate for these tube resonances by adjusting the calibration of the hearing aid. Unfortunately, once the audiologist changes the settings or tube length from those prescribed at the factory these potentially disturbing resonances reappear. Therefore, the inherent limitations of traditional hearing aid design remains a problem and

canal to preserve sound quality. To ensure optimum performance in even the most challenging of listening situations, Delta takes advantage of Oticon's unique Artificial Intelligence technology⁵. This implies that various clarity enhancing solutions such as MultiState Adaptive Directionality and TriState Noise Management are implemented when it provides a measured benefit.

High Frequency Performance and Sound Quality

A key to improved speech understanding in noise is to ensure that speech information in the higher frequencies is made salient without any audible

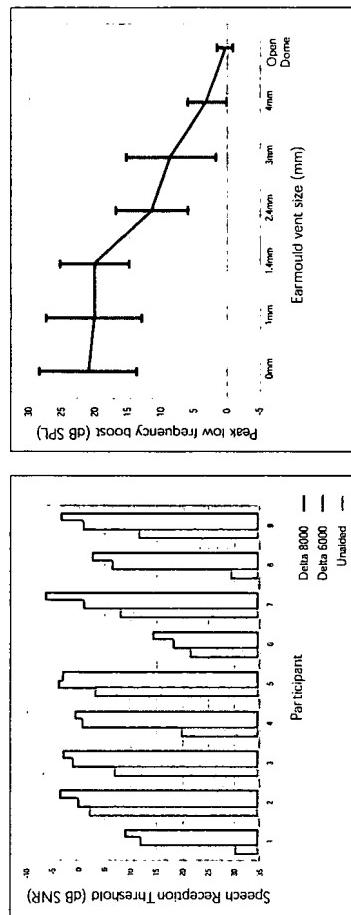


Figure 4: Comparison of consonant identification performance of 11 participants on a test of consonant identification in noise. It is clear that Delta provides not only a significant improvement, but also that the performance improves when the bandwidth is extended to 8000Hz.

Figure 5: Open ear responses from different vent diameters, indicating that the OpenDome has the same response as a totally open ear canal.

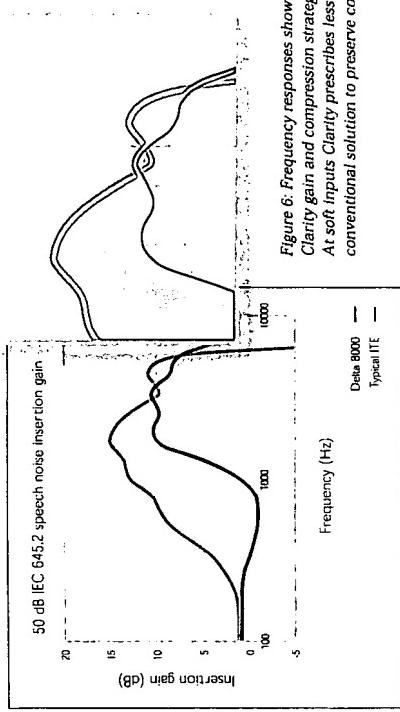


Figure 6: Frequency responses showing the unique Clarity gain and compression strategy in Delta. At soft inputs Clarity prescribes less gain than a conventional solution to preserve comfort.

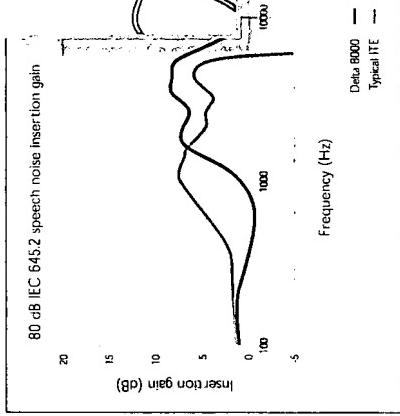


Figure 7: At loud inputs, i.e. speech in noise Clarity benefits from the extended bandwidth in Delta to deliver extra high frequency amplification to improve speech understanding.

mixing of the direct sound and amplified sound. This mixing of sound sources results in the need to develop a totally different amplification strategy and provides the possibility to provide less gain than would ordinarily be prescribed in traditional hearing loss compensation strategies. Therefore, it is crucial to design the rationale with both the user's need for speech understanding in noise and occlusion free fitting (mixing of direct and amplified sound).

Amplification for speech loss correction

(a) Clarity enhancement

Providing better speech understanding requires that our amplification strategy ensures extended high frequency information in louder listening environments (Figure 6 and Figure 7). To preserve a natural sound quality, Delta sparingly implements compression. We do not provide low frequency amplification because of the combination of good low frequency hearing and open fittings. This eliminates the risk of upward spread of masking, and ensures that good speech understanding in quiet situations is retained. In addition, unlike conventional hearing solutions, Delta does not require vent compensation.

situations. What they wish for is additional clarity in difficult-to-understand situations.

Audiologically, it is clear that the combination of significant low frequency hearing and a mild-to-moderate loss in the higher frequencies results in good speech understanding in quiet listening conditions. However, when listening becomes more difficult in background noise, assistance is required. This assistance must be provided in a way that preserves natural sound quality.

Improved speech understanding in background noise is achieved by:

- Focusing amplification in the high frequency region with little amplification for the low frequency speech sounds. Reducing low frequency gain prevents upward spread of masking and improves sound quality.

- Implementing compression sparingly to preserve natural sound quality, and to ensure that the maximum amount of temporal and spectral cues are available for speech understanding in difficult listening situations.

With Delta, we compensate less, delivering a different mix of amplified and direct sound, which is an essential ingredient for excellent sound quality¹. Compared to typical wide dynamic range compression algorithms, the Clarity rationale does not try to fully correct for the hearing loss but enhances the speech information by using the extended bandwidth to deliver additional high frequency information. Improved speech understanding in background noise is achieved by:

- Setting the compression knee point to 50 dB SPL to ensure audibility of soft consonant sounds in noise, without being so low that it provides annoyance in quiet.
- Enhancing listening comfort in loud environments (>80dB SPL) so that for very high inputs there is no amplification (0 dB gain).
- Providing less insertion gain which reflects the clarity needs of the listeners and the benefit achieved by mixing the amplified and direct sound sources.
- Having fast release times (80-320ms) combined with slower attack times (5-10ms) to match amplification speed with the good residual auditory capacity of the listeners. This allows the maximum preservation of speech cues and the opportunity to "listening in the dips".

(a) **Delta Memory**
The Delta Memory collects the data recorded by Delta on the hearing instrument's operation. It then analyses and displays it as an Envirogram in the Ceph 7.0 fitting software². The audiologist can now quickly confirm that the operation of Delta using Artificial Intelligence has provided benefit to the patient. In addition, the Envirogram³ allows the audiologist to quickly gain access as to how Delta's systems have benefited the patient. The audiologist can furthermore use the Envirograms to demonstrate to the client how Multiband Adaptive Directionality and TriState Noise Management specifically add value to the client in their actual daily listening situations. Similarly, the audiologist can use the Envirograms to explain to the client the types of listening situations they are in and how Delta provides specific solutions for them. Therefore, the Delta Memory is an integrated part of the Delta fitting giving a quick and easy demonstration of the benefit to the client using their actual listening experiences.

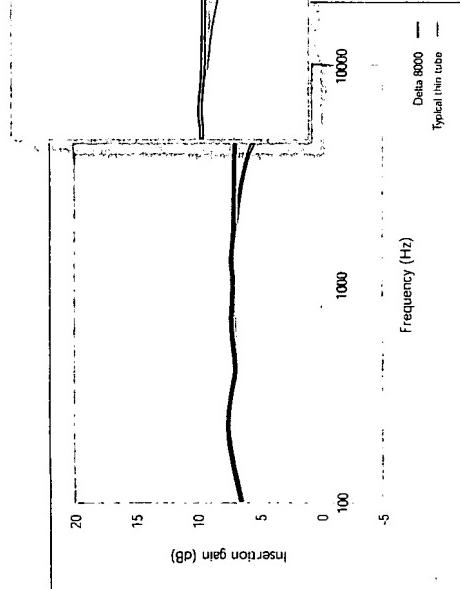


Figure 8. Graph of the DI by frequency indicating the preservation of high frequency directivity in Delta obtained by ensuring a microphone port spacing of 9mm against a standard BTE shell casing.

(b) Multiband adaptive directivity
To maximise speech understanding in noise, we must make use of directional microphones – the only proven method to improve speech understanding¹¹. The benefit of directability with open fittings has, however, been questioned. The argument being that by opening the vent you loose the processed signal and allow the natural sound to reach the eardrum, thus reducing the benefit of directability. Fortunately, various reports¹²⁻¹⁴ have demonstrated that it is possible to maintain directability with a totally open fitting. The key to this is to ensure that the directional microphone maintains a good high frequency response^{3,14}.

For Delta, maintaining the directional benefit was of paramount importance. One of the key design decisions was to ensure that directability was not only maintained but also enhanced for the high frequencies. While directional benefits rely on a physical separation between two microphones, having too great a distance between microphones results in loss of directivity in the high frequencies. For Delta, we determined that the optimum port placement was 9mm, as opposed to the usual 12-13mm found in most conventional BTE instruments. This allowed us to maintain

noise by applying noise reduction or notch filtering techniques. These strategies apply other processing artefacts but are rarely successful. A more intelligent solution is to reduce the velocity of the wind before it reaches the microphones.

directionality at the theoretical limit of 6dB throughout the high frequency region (Figure 8). Similarly, the Delta design ensures a good horizontal position of microphones and ensures the correct distance between the microphones (Figure 9).

To further maximise directability, it is crucial to recognise that noise sources are not stationary within the sound environment. Similarly, complex listening situations also involve multiple noise sources that differ by frequency. Therefore, we need an adaptive directivity system that can not only track and adjust the polar response to provide the maximum signal-to-noise ratio possible, but is also able to adjust this across three separate frequency regions to attenuate multiple noise sources simultaneously.

As wind noise is often a problem for people with a hearing loss and in particular mild to moderate hearing loss in the high frequencies, a clever solution is required. Directional microphones are extremely sensitive to wind noise which often results in decreased satisfaction and reports of poor sound quality¹²⁻¹⁴. Previous solutions have mainly focused on attempting to digitally process out the effects of wind

In Delta, an exchangeable top "grid" above the microphones acts as a combined wind and dirt protection (Figure 10). This grid acts by significantly slowing down velocity of the air just in front of the microphones thus lowering the impact of wind. Importantly, the patented grid was designed to ensure high directivity.

While directability provides many advantages, it is not, however, the solution for every possible listening environment¹⁵. Therefore, Delta is driven by Artificial Intelligence that calculates the signal-to-noise for any given listening situation and ensures that directability will provide a benefit before enabling the system. This removes the unfortunate situations known from other systems where important signals from behind are cancelled. Similarly, the wearing of full time directional system provides an audible distortion to the listener's sound scene thus providing further loss of transparency. Artificial Intelligence is the key to ensure that the system is only working when it provides a benefit.

Figure 10. The wind filter on the Delta instrument protects the two directional microphones by reducing the velocity of the wind before it reaches the microphones.

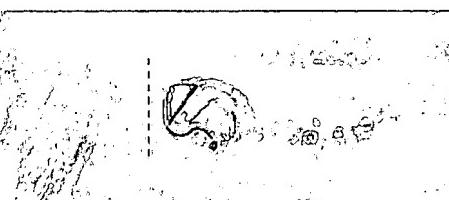


Figure 9. The Delta design ensures a horizontal placement of the two microphones

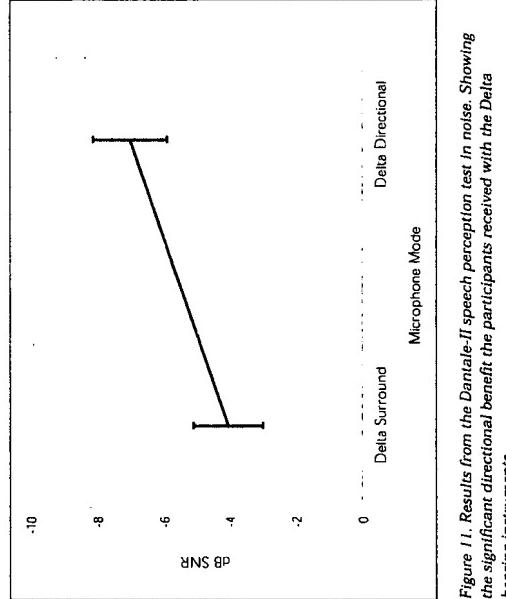


Figure 11. Results from the Dantale-II speech perception test in noise. Showing the significant directional benefit the participants received with the Delta hearing instruments.

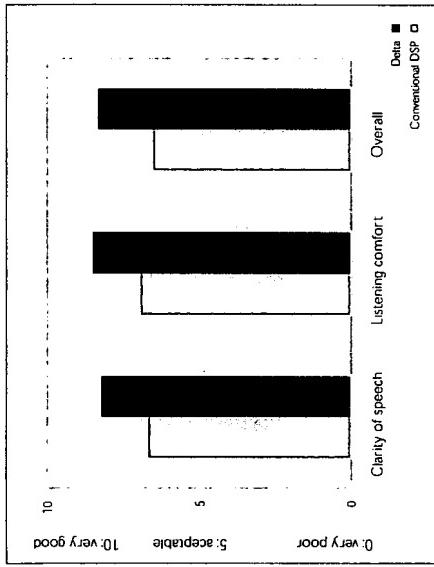


Figure 12. Comparison of performance with Delta versus conventional premium hearing aids on the dimensions of clarity of speech, listening comfort and over-all.

Conclusion
Delta provides an unrivalled degree of performance for people with a mild to moderate high frequency hearing loss. Importantly, the cosmetic benefits and size do not come at the cost of other features or sound processing options. The approach taken by Delta is audiological novel. The purpose is not to fully correct for the hearing loss, but to focus on providing the best possible speech understanding in difficult listening situations. In this way, Delta meets the needs of people who have good low frequency hearing and mild to moderate high frequency hearing loss.

Similarly, in addition to refocusing our thoughts in terms of sound processing, Delta also augments the Clarity rationale with the most advanced automatic features (Multiband Adaptive Directionality and TriState Noise Management) governed by the only hearing aid chip platform that is capable of Artificial Intelligence processing. To ensure that occlusion is never an issue, Delta provides a totally open fitting concept, allowing the balanced mix of natural and amplified sounds. Similarly, to ensure the best possible sound fidelity

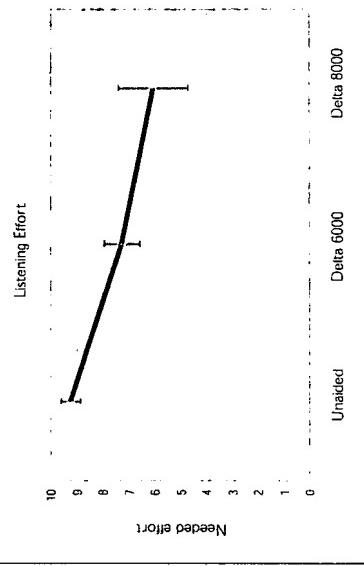


Figure 13. Reduction in the client's perception of listening effort required to listening to speech in difficult listening situations, showing the improvement provided by both the Clarity rationale and also the extended high frequency bandwidth.

Performance of Delta
Good design by itself cannot guarantee that the solution will meet the needs of the listener. It is therefore essential to carefully evaluate the performance of Delta against other more conventional solutions. Figure 12 illustrates the reported performance benefits of a group of hearing aid users who were wearers of conventional premium digital hearing aids with advanced features such as multiple channel non-linear amplification, directionality and noise reduction. What can immediately be seen is that while the conventional digital hearing instruments provide a

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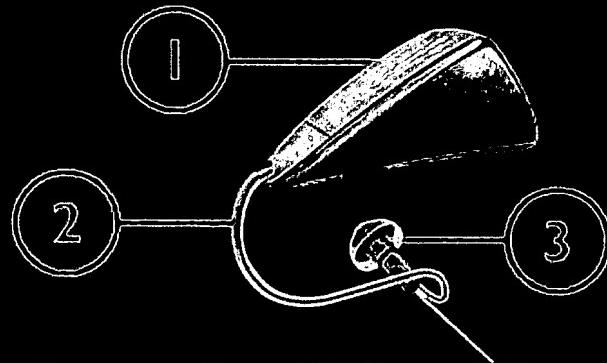


People first

We believe that it takes more than technology and audiology to create the best hearing instruments. That's why we put the individual needs and wishes of people with hearing loss first in our development of new hearing care solutions.

EXHIBIT 6

Oticon • Delta

[Home](#) | [Contact us](#) | [t](#)[Home](#)**Design**[Colours](#)[Discreetness](#)**Shape**[Performance](#)[Speech-in-Noise Test](#)[About Clarity loss](#)[Your opinion matters](#)**Triangular hearing**

Delta's unique shape affords an optimal position for two, state-of-the-art microphones, enabling Delta to cancel out up to three noise sources from different directions and focus on the important speech signals. The result is superior speech understanding in a full sound picture.

Delta's unique, triangular shape also ensures maximum comfort when sitting behind your ear. Weighing less than two grams, Delta delivers big benefits via a light and comfortable design.

1. Amplifier

Unique triangular shape ensures optimal position for two state-of-the-art microphones

2. Thin sound wire**3. Speaker + dome**

Placed in the ear canal to offer unmatched performance and comfort

How to buy Delta

[Click here to find a hearing center near you](#)

Hearing care professional**Tell a friend****Send a mail**

EXHIBIT 7

News

- > **Mar. 2006**
- > **Dec. 2005**
- > **Jul. 2005**
- > **Mar. 2005**
- > **Jan. 2005**
- > **Aug. 2004**
- > **Apr. 2004**
- > **Jan. 2004**

New Product Release: LEONARDO II family

Delivery situation:

Leonardo II and Leonardo II Open are fully available for regular supply. Leonardo II Natural: Due to necessary changes for the external receiver itself, we will only be in a state to supply the Leonardo II Natural in quantity end of May 2006 onwards.

In the interim only sample requirements for testing or homologation purposes can be fulfilled by us without delay.

By the way, also the standard Leonardo II with the unique and patented push-scroll function as well as the Leonardo II Open are excellent products. A good chance to try these out first, to get acquainted with the latest Leonardo II.

New Product Release: FREE SOUNDMANAGER

(Free VC Open: Delivery has started, the interest and demand from all our customers side is enormous, as well as the backlog of booked orders! We expect to have full ability of supply by mid of April.)

Free VC: Available for the time being for sample requirements for testing or homologation purposes.

Further, to avoid any confusion we like to inform you about the fact that the FREE SOUNDMANAGER is called SOUNDMANAGER in the USA. This is due to the reason that one competitor is already using the name. The product itself is identical.

UPGRADE OF THE VITAL TECHNOLOGY

The new VITAL II technology is now available in all different styles (BTE/CIC/Mini Canal/ITC and ITE). This is why we would like to introduce the new technology to you in this first Hansaton Newsletter of 2006.

COMPARISON Vital old / VITAL II (new)**Vital (old)**

- 4/3 structure (Gain/AGC)
- Directional microphone
- Feedback management (use of notch filters)
- Modification necessary for use of MLx mode
- Fixed frequency and loudness of the signal tone for program switch or empty battery

VITAL II (new)

- 8/4 structure (Gain/AGC)
- Directional adaptive microphone (under "Automatic")
- Feedback management (phase inverter)
- MLx compatible by default

- Frequency and loudness of the signal tone can be customised with the software

Advantages/Customer's benefits

- Optimal frequency shaping possible for all types of hearing losses
- Suppression of static and moving sources of noise
- More effective feedback management and without reduction of the required gain
- No modification necessary
- Customisation of the frequency and/or loudness according to customer's requirements

VITAL HAS CHANGED:

Thus the signal processing of the VITAL has been completely overhauled so that it continues to satisfy the requirements placed on a digital hearing system in the medium level.

The multi-microphone technology now not only reduces static sources of noise based on the directional microphone system, but also facilitates the reduction of moving sources of noise. To do this, you will have to activate the CANCELLER function of the Situation Manager.

Secondly, the Speech Detection in VITAL II works actively, and consequently. It not only effectively reduces noise simultaneously boosts relevant speech portions in real time. This leads to a significant improvement in the perception of speech in acoustically complex situations.

Lastly, the feedback management system has also been completely overhauled. The tried and tested filter has been replaced by a system which suppresses feedback without reducing required amplification and can do this without forfeiting acoustic benefits. Measurements of critical gain is also available to allow the system to be optimised if required.

We are confident that these up-dates in technology will please your patients and customers.

Finally, VITAL now offers more technology for a lower price compared to the old Vital!

Should you have any further questions with regards to the new VITAL instruments please do not hesitate to contact your responsible Sales Co-ordinator or mail to:
New Vital Infos

reddot design award for the FREE SOUNDMANAGER:

In our last edition we have already informed you that the unique product of Hansaton has won the iF product design award. On top of that we have just been informed that Hansaton has also won the reddot design award 2006 with the FREE SOUNDMANAGER.

This year, the jury has received more than 2.000 transmittals from 41 countries.

You may like to visit the reddot design award homepage to find out more about this prestigious award.

The official ceremony will be held on the 26th of June in Essen. Here we will receive the official certificate and as Hansaton partners may start to use the logo in your marketing activities as of now.

HANSATON on the AAA:

Hansaton will, for the second time, participate at our industry's biggest exhibition: The AAA which is held in Minneapolis. The show will start on the evening of April 5th and last until Saturday, 8th April at 2pm.

Hansaton will have an even bigger booth than last year and if you are planning to attend the meeting please let us know in advance. Should you know of any of your partners, customers or other contacts who will attend the AAA please let us know in advance to booth 606/607!

'Open' fitting advise:

We like to give you a fitting advise for all instruments using the 'Open' formula:

If you choose the formula 'Open' you should always measure the critical gain before executing the first fit integrated in the software under the Acoustical Parameters and can be measured with the Open Loop Gain (OLG). The critical gain will be calculated on an individual basis for each patient. This results in the hearing with less feedback.

The measurement will be executed per microphone, meaning one run if the microphone settings is on or two programmes or two runs if you have chosen directional in one programme.

Should you have further questions with regards to hearing instrument fittings you may like to send an email to Tanja Lendrath:
Email to Tanja

5,000 US\$ donation for Amor en Accion, Honduras:

Everyone who participated in our International Foreign Agent Meeting 2005 in Nuremberg may well remember the donation for hearing impaired children in Honduras. Together with your help we have donated the US\$ 5,000. Thank you again for your participation and help.

Business-Select:

Password:



EXHIBIT 8

FREE SOUNDMANAGER

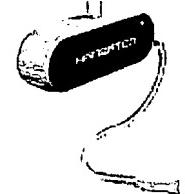
- > free
- > virtually invisible
- > experience
- > open
- > active
- > reliable


HANSATON
SOUND

Free.

Feel free - always and everywhere with the FREE SOUNDMANAGER.

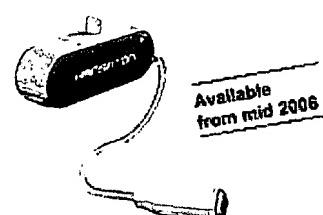
Communicating with other people defines our lives and is often decisive for the quality of life or success: at leisure, in sports, socially or at work. However, constantly growing environmental and noise pollution lead to more and more people with hearing impairments or Tinnitus (constant ringing in the ears). Understanding and listening can then become a problem in certain situations.

**The FREE SOUNDMANAGER - for the important and enjoyable moments in life.**

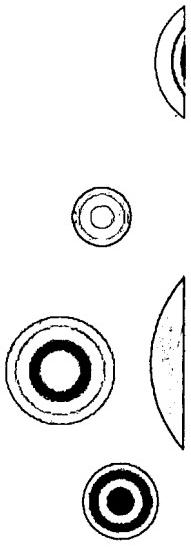
The FREE SOUNDMANAGER now brings you discreet and virtually invisible help. It guarantees complete understanding just when you need it. The newly developed design housing is extremely comfortable, barely visible, and reliable at all times. This is guaranteed by the most modern, high tech electronics.

The FREE SOUNDMANAGERs - 2 strong characters for all applications**FREE SOUNDMANAGER OPEN Variant**

This system gets by without conventional earmoulds. Just put on and enjoy. You will love the FREE SOUNDMANAGER.

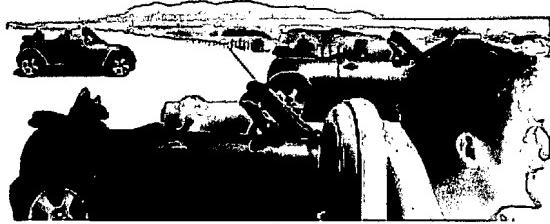
**FREE SOUNDMANAGER NATURAL Variant**

Experience the future superlative sound with the innovative natural technology. The receiver placed directly in the auditory canal with its almost invisible link enables excellent hearing enjoyment.



FREE SOUNDMANAGER

- > free
- > virtually invisible
- > experience
- > open
- > active
- > reliable



Open.

The FREE SOUNDMANAGER - anything but ordinary.

Virtually invisible design and wearing comfort are the basic ideas behind the FREE SOUNDMANAGER.

Open design and maximum wearing comfort - the trademarks of the FREE SOUNDMANAGER.

Choose between mini tube or natural technology: The "open" design of both versions offers you an extremely pleasant wearing comfort and a very natural sound. That's what makes the FREE SOUNDMANAGER stand out from normal hearing systems. Its new design cuts out unpleasant closure effects or pressure points from the start. You won't feel the FREE SOUNDMANAGER at all any more after just a short while.

Virtually invisible
is the modern ergonomic design with invisible mini tube.

Pleasantly comfortable to wear
thanks to the open design with mini tube and low weight.

Natural sound
due to natural sound technology. An unforgettable hearing experience of superlative quality. You will be thrilled.

Optimum understanding
state-of-the-art digital technology guarantees perfect understanding in all situations.

Intelligent technology
which automatically adapts to your personal hearing requirements and life situations.

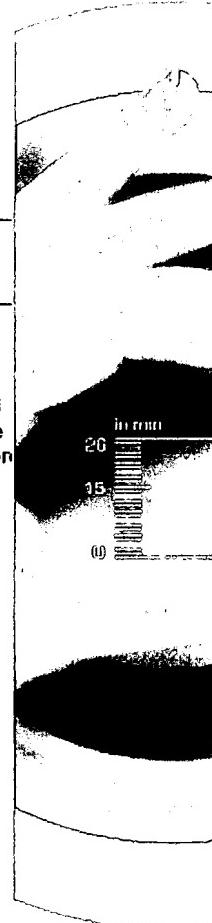
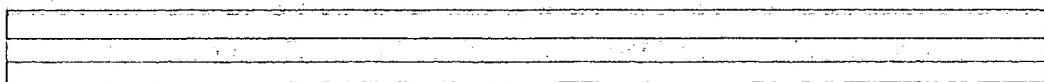


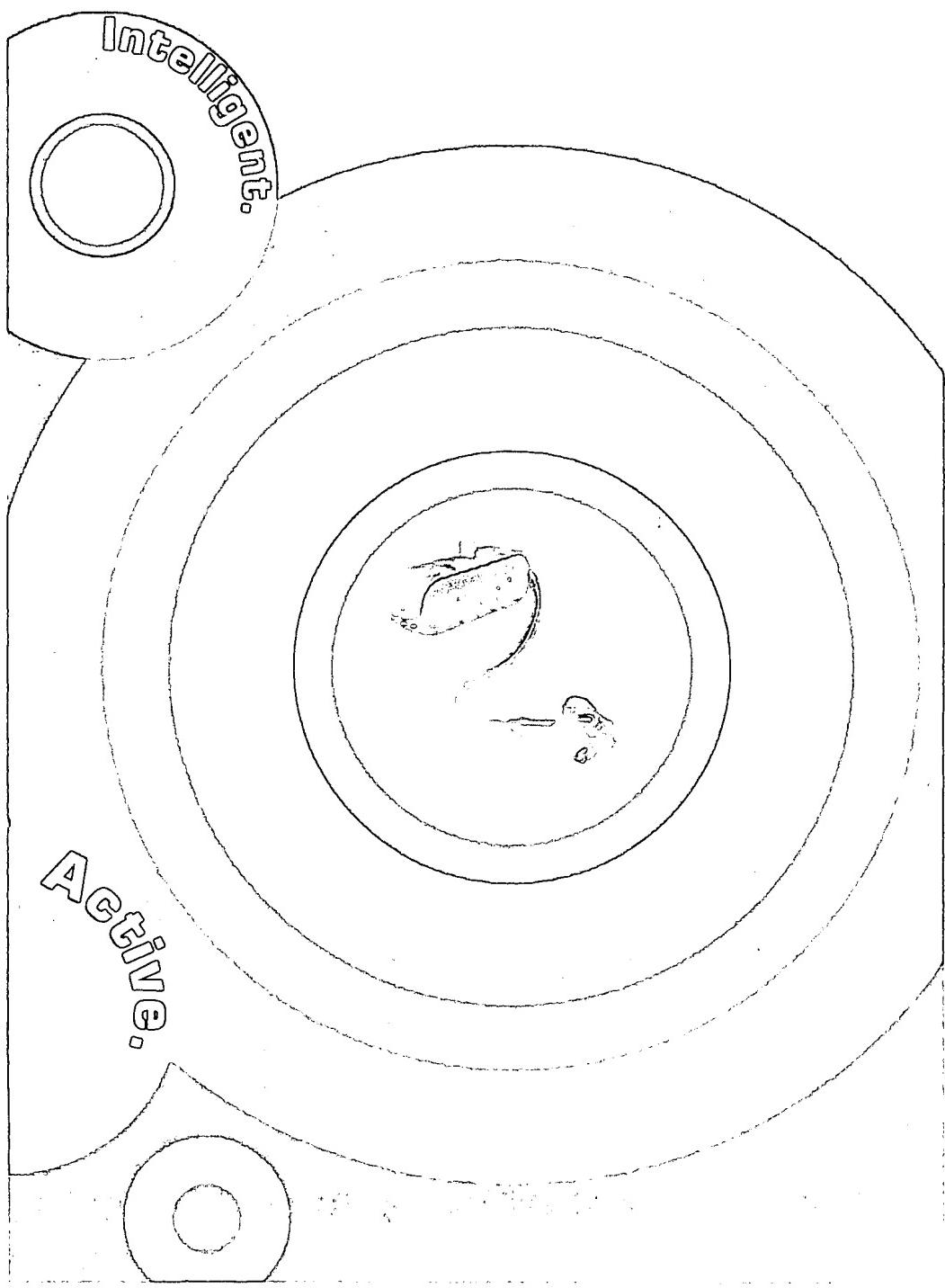
EXHIBIT 9

HANSATON
FREE
SOUNDMANAGER



Hearing without a hearing system.

Free.



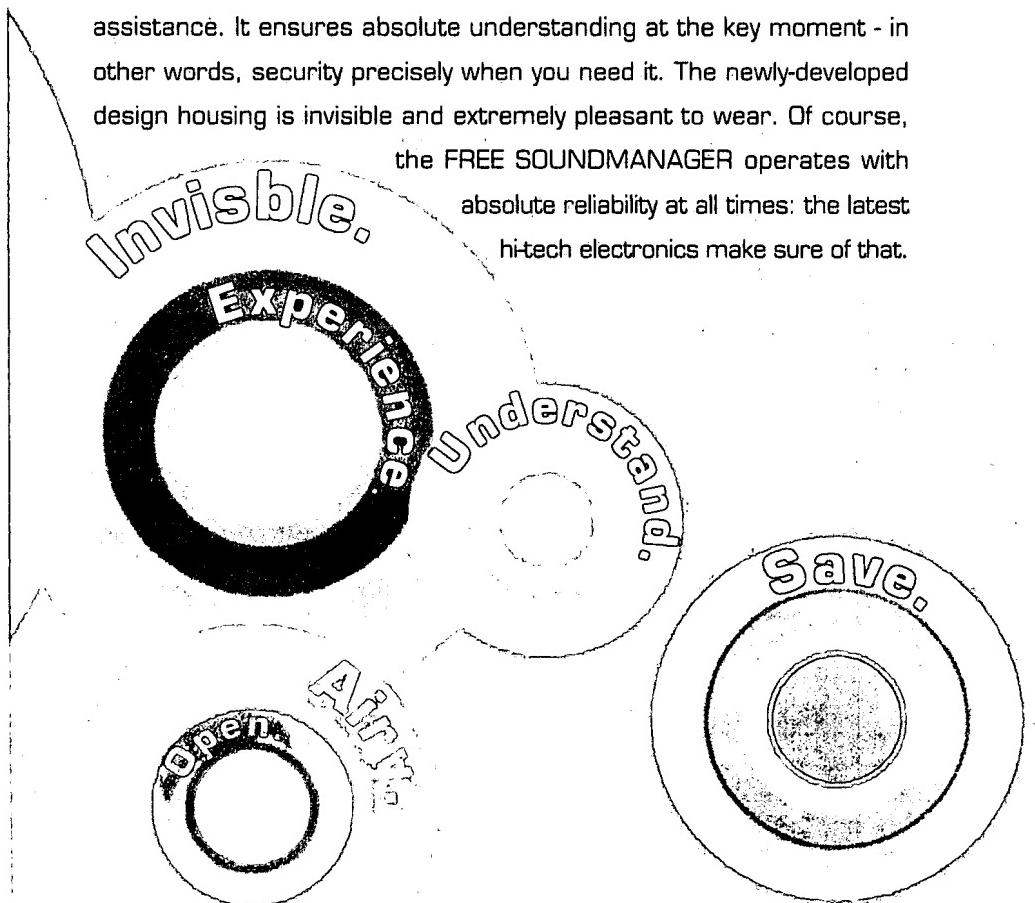


Feel free - all the time, wherever you are, with the **FREE SOUNDMANAGER**

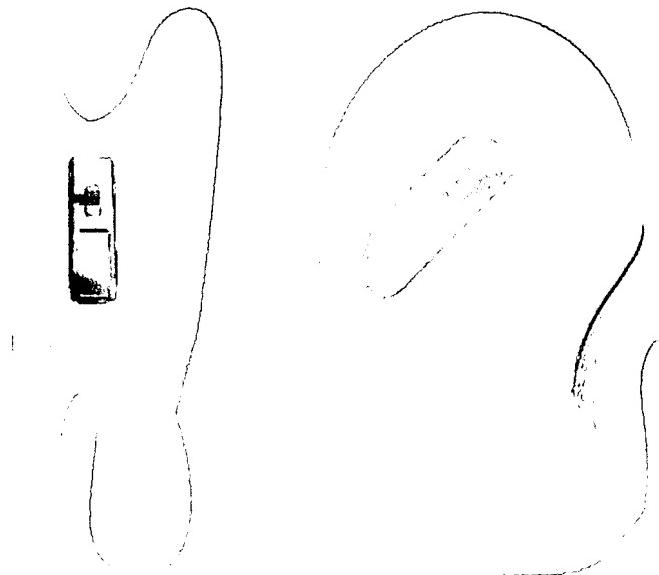
Our lives are determined by communication with other people. Communication is often also a deciding factor in greater quality of life or success, whether in leisure, sport, social activities or at work. More and more people, however, are developing impaired hearing or tinnitus (continuous noise in the ears) as a result of steadily rising environmental and noise pollution. Understanding and listening can then be a problem in certain situations.

FREE SOUNDMANAGER - for the important and wonderful moments in life.

The **FREE SOUNDMANAGER** now gives you discreet and invisible assistance. It ensures absolute understanding at the key moment - in other words, security precisely when you need it. The newly-developed design housing is invisible and extremely pleasant to wear. Of course, the **FREE SOUNDMANAGER** operates with absolute reliability at all times: the latest hi-tech electronics make sure of that.



MOVING SHOE



**FREE SOUND MANAGER is
characterised by:**

> an innovative shape

> maximum hearing comfort

> minimal weight

> optimum wearing comfort





FREE SOUNDMANAGER - your invisible companion in every situation you encounter

The FREE SOUNDMANAGER is located **invisibly and securely** at the ear. Its new shape ensures that it is reliable, whatever the situation. It is also true for both versions of the FREE SOUNDMANAGER, whether with mini tube or Natural receiver, that the cosmetic tube (size just 1.3 mm) cannot be seen at the ear.

It is perfectly adapted to the shape of the ear.

You will be impressed by the **unique wearing comfort** of the FREE SOUNDMANAGER: you won't notice the instrument at all after just a short time. This is due on the one hand to its ideal fit and innovative design. On the other hand, the FREE SOUNDMANAGER is just a featherweight at 1.8 grammes. You can't feel anything and no-one else can see anything - a good feeling all round!



Experienc!

> **Sound management**

for hearing and understanding without whistling

> **Feedback suppression**

for specific improvement of the hearing experience

> **Noise suppression**

for an optimal hearing comfort also in quiet environments



CE

HANSATON
FREE
SOUNDMANAGER

The FREE SOUNDMANAGER - brings life to your ears

The latest digital technology in the FREE SOUNDMANAGER guarantees you optimum hearing and thus perfect understanding. The specially developed hi-tech electronics automatically adjust to your hearing requirements to give you security in every situation you encounter.

For people who want more from life.

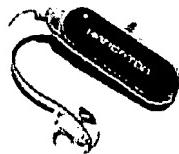
The intelligent technology enables you to be in unobtrusive command of the important moments in life. This is because the FREE SOUNDMANAGER is the ~~only instrument to combine two benefits~~. It provides ~~top-of-the-range audiological performance~~ and remains ~~virtually invisible~~ in the process. You experience everything as if your little companion were not there at all.



Open .

> As good as invisible

Modern ergonomic design with invisible wearing tube



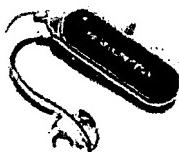
> Pleasant to wear

Thanks to its open design with 1.3 mm mini tube and light weight



> Natural tone

thanks to Natural sound technology. An incomparable top-of-the-range tone experience: you will be impressed



> Optimum understanding

The latest digital technology guarantees optimum understanding in every situation



> Intelligent technology

Adapts automatically to your personal hearing requirements and the situations you encounter.





FREE SOUNDMANAGER - anything but ordinary

"Invisible design" and extraordinary wearing comfort are the fundamental principles behind the FREE SOUNDMANAGER. A wearing comfort which the latest technology makes far superior to that of conventional wearing systems.

Open shape and maximum wearing comfort are the trademarks of the FREE SOUNDMANAGER.

Select between mini tube or Natural technology: the open design of both variants gives you an extraordinarily pleasant wearing sensation and particularly natural tone. This differentiates the FREE SOUNDMANAGER from normal hearing instruments.

Its new design means that unpleasant occlusion effects and pressure points do not occur at all. After only a short time, you won't feel the FREE SOUNDMANAGER at all.



Active.

> **Automatic noise suppression**

Noise, machine noise and the like are detected and suppressed.

> **Intelligent feedback management**

Rules out unpleasant feedback or whistling noise.

> **Digital speech detection**

Improves the understanding of speech in
a noisy environment.





FREE SOUNDMANAGER.

**Be mobile and active - hearing comfort
in every situation.**

Your hearing instrument specialist programmes the FREE SOUNDMANAGER in exact accordance with your individual requirements. He takes into account your personal preferences, habits and hobbies, matching the instrument to you perfectly. In all this, he has just one objective: you should be able to hear perfectly in every hearing situation!

- | Enjoy an active, unrestricted life - with the
FREE SOUNDMANAGER.



Sawie

You can rely on the **FREE SOUNDMA**

A reliable and pleasant start to the day.

Have an easy, relaxed start to the day with the FREE SOUNDMANAGER: pleasant to wear, easy to put in and perfectly adjustable to your mood using the integrated volume control. A little quieter in the mornings? Just as you want!

Optimum understanding in every situation.

Whether at work, when shopping or in conversation: The FREE SOUNDMANAGER gives you the discreet, invisible security you need. Stand in the middle of life and miss nothing - thanks to your invisible companion.





NAGER 100 per cent - round the clock

Full performance in sport and leisure.

Be active in sport and leisure or when travelling: The FREE SOUNDMANAGER opens up new opportunities. React quickly and spontaneously in every situation, enjoy each moment without restriction - easy listening for an active life.

Free your mind – enjoy the moment.

Let the day come to an enjoyable end by socialising with friends or listening to music. The FREE SOUNDMANAGER is the unobtrusive companion which keeps you in command. With its Natural sound reproduction of tone, it gives you an incomparably natural, pleasant hearing experience.

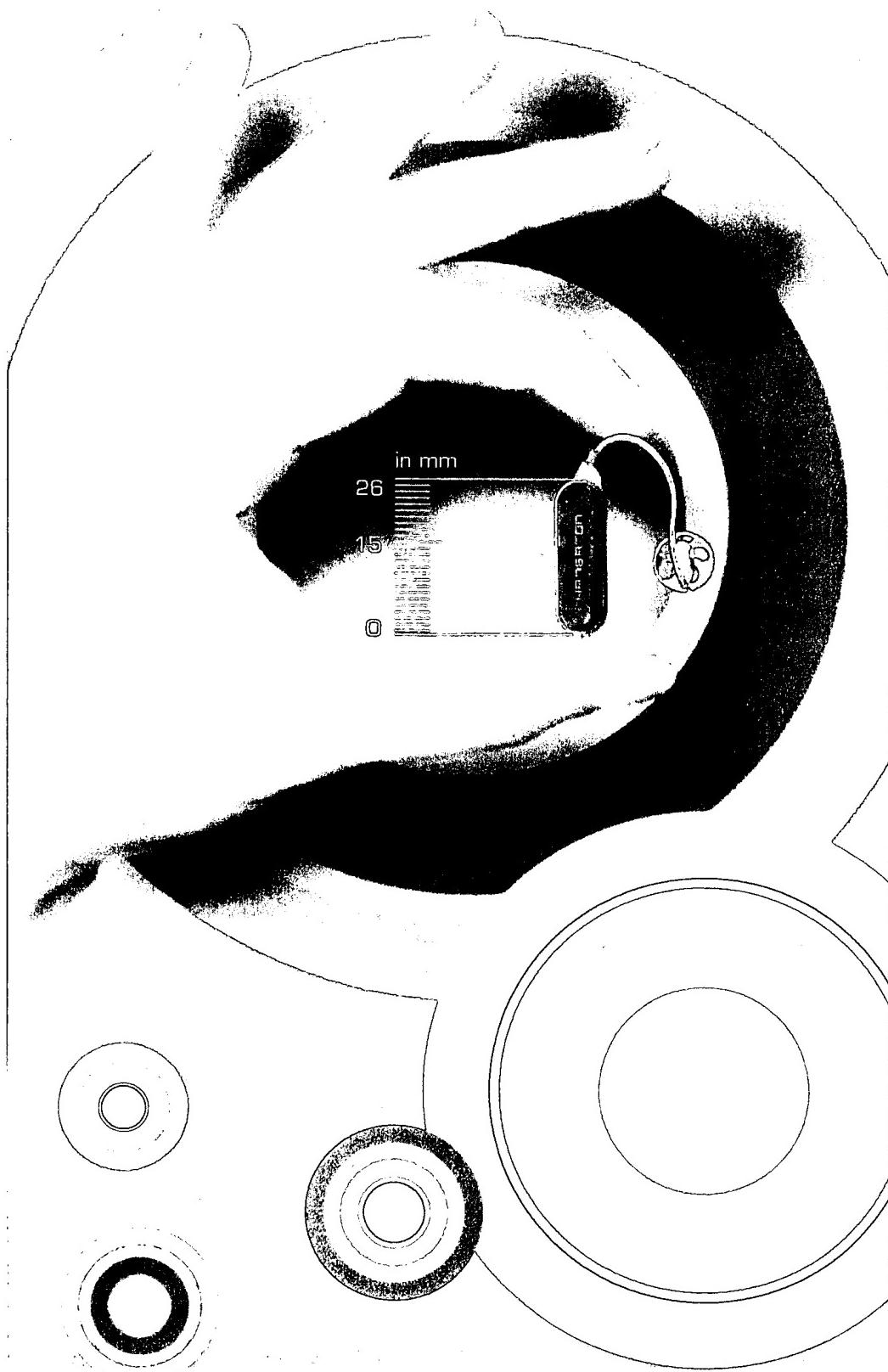
2



3



Airy.





FREE SOUNDMANAGER - unbelievably small and much more than a hearing instrument

Small, invisible, comfortable and easy to use. Support exactly when you need it. At last there is a product which precisely meets the requirements you have of modern communication products today. Take your freedom - with the FREE SOUNDMANAGER.

Your personal experience of hearing and your individual preferences decide: open fitting or Natural sound technology!

FREE Open SOUNDMANAGER

Invisible mini tube means perfect cosmetic appearance. Can be individually matched, with pleasant "open" wearing comfort. Design housing and the latest generation, fully automatic digital signal processing individually adapted to your personal wishes and requirements. Manual volume adjustment if required.

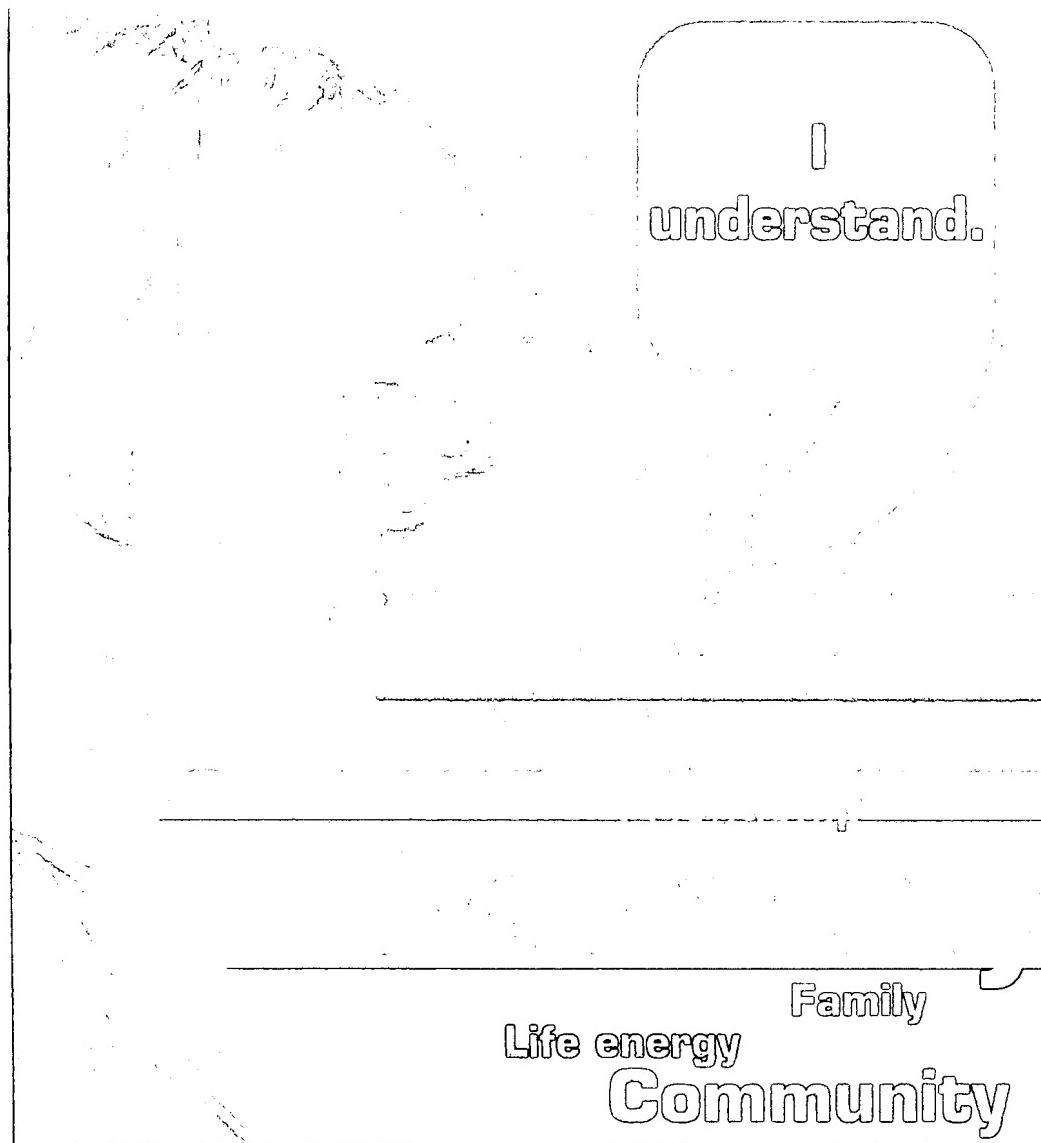
FREE Natural SOUNDMANAGER

The new tone experience with a pleasant, natural tone never before achieved. Invisible cosmetic design. Open wearing form for the most natural, pleasant wearing comfort. Can be individually matched to your personal wishes and requirements. Design housing and latest generation, fully automatic digital signal processing. Manual volume adjustment if required.

Understa

FREE SOUNDMANAGER - Don't just hear better - understand ev

It is often not just hearing alone which is the problem, but rather understanding properly. You notice this when talking in large numbers of people, when shopping or in front of the television. The first instrument really to help here, in contrast to classic hearing instruments, is the FREE SOUNDMANAGER. The latest digital chip technology means it can guarantee optimum understanding in virtually all common situations, fully automatically, in every environment, precisely when you need it.



and

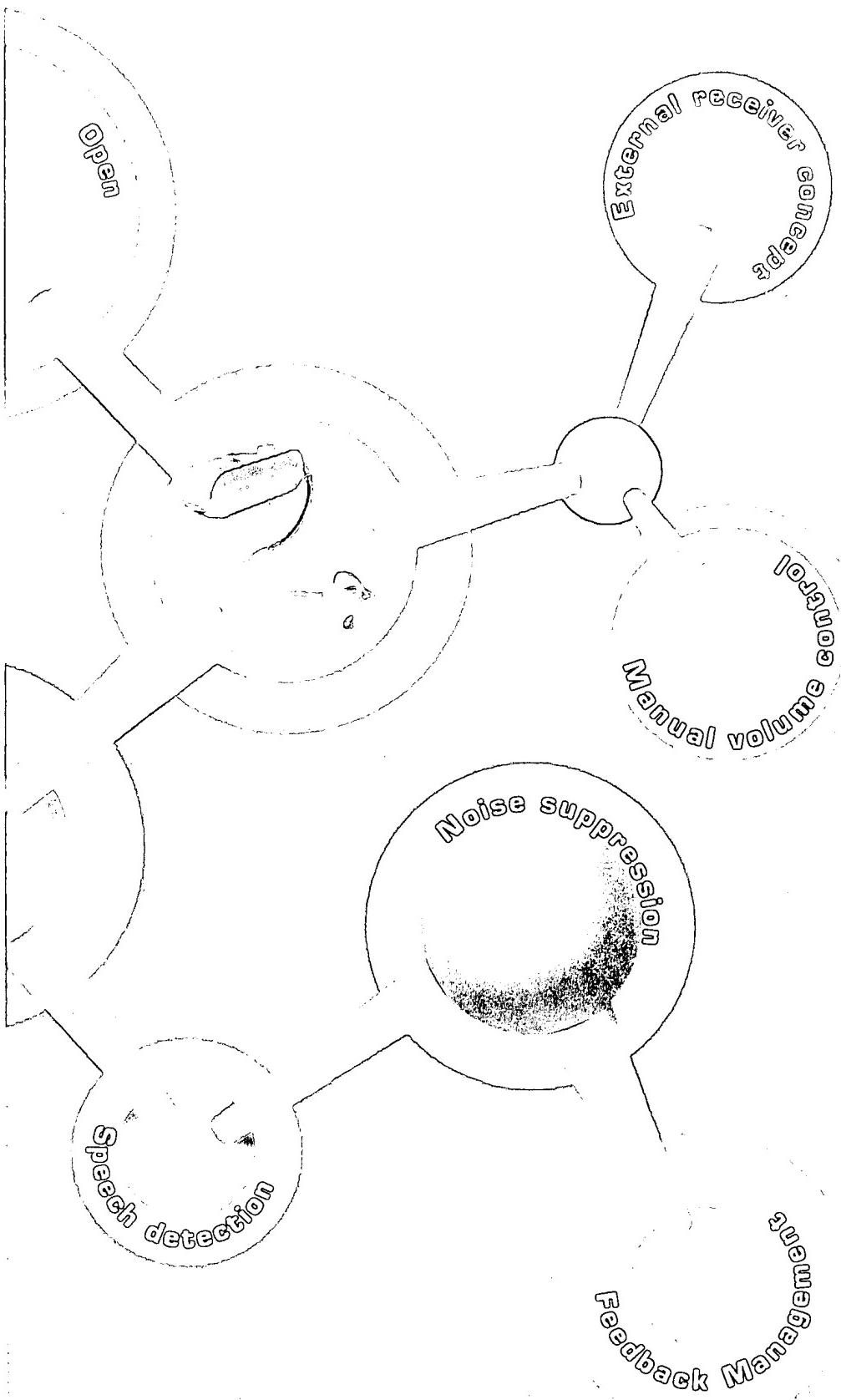
HANSATON
FREE
SOUNDMANAGER

erything properly too!

Its forward-looking technology makes the FREE SOUNDMANGER the perfect companion for your needs. In collaboration with your hearing instrument specialist, you will define your personal settings and have your FREE SOUNDMANGER individually programmed in accordance with your requirements and preferences. The virtually invisible tube system is also perfectly matched to suit you. Adapted to suit the individual anatomy of your ear, it guarantees a perfect fit and the best possible function.



Intelligent





FREE SOUNDMANAGER - the comprehension genius

> **Open**

For some types of hearing loss, a mini tube can be used to route sound from the hearing system into the ear. This is cosmetically unobtrusive and does not have the negative effects of an occluded ear as classic systems do.

> **External receiver concept**

The receiver to generate the sound is positioned in the auditory canal. As the auditory canal is not blocked with the external receiver, a natural, balanced tone results. A cosmetically perfect system.

> **Manual volume control**

FREE is a system which works completely automatically. If you want to make an individual change to the volume, this is no problem: this manual change is possible on the FREE SOUNDMANAGER.

> **Noise suppression**

Acoustic systems generate their own internal noise which becomes audible in a quiet environment. The FREE SOUNDMANAGER suppresses this irritating noise.

> **Speech detection**

The objective is pleasant hearing and straightforward understanding. This is why with FREE SOUNDMANAGER, speech is filtered out of the whole acoustic signal and processed further in the form of an individual signal.

> **Feedback management**

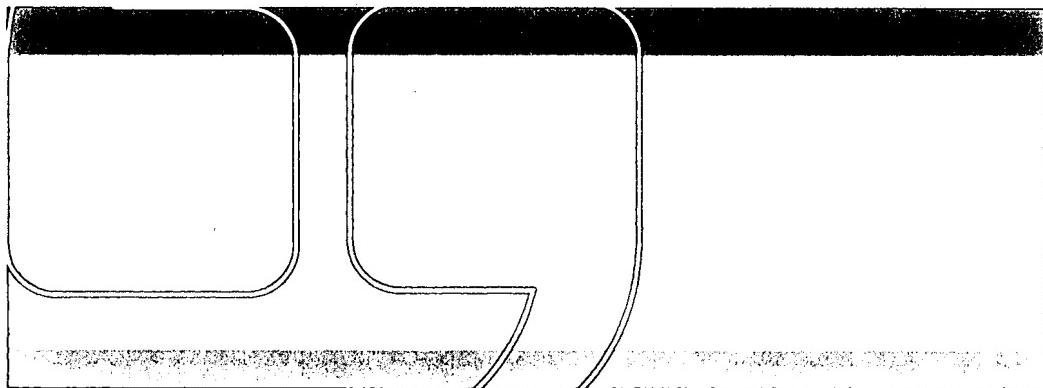
Whistling hearing instruments are irritating for users. The FREE SOUNDMANAGER detects feedback, suppresses it and ensures that wearing the system is pleasant without any irritating whistling.

Hear better, understand better.

For over 50 years, Hansaton has been using innovative hearing systems and technologies to help people hear better again. It has always been our aim to give people the opportunity of leading a better life.

We have succeeded in this aim over and over again using progressive technologies and innovative ideas. We develop our products in close collaboration with the University of Cambridge. This enables us to design products which are always state of the art in both scientific and audiological terms.

Your hearing instrument specialist, too, plays an important role here. He helps with all your questions and of course in selecting your individual FREE SOUNDMANAGER. Years of experience and professional skill in hearing can only be obtained from a hearing instrument specialist, so you can only order the FREE SOUNDMANAGER hearing systems from specialists.



For more information on the FREE SOUNDMANAGER,
please visit our website: www.hansaton.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Leon Hirsch declares and says that:

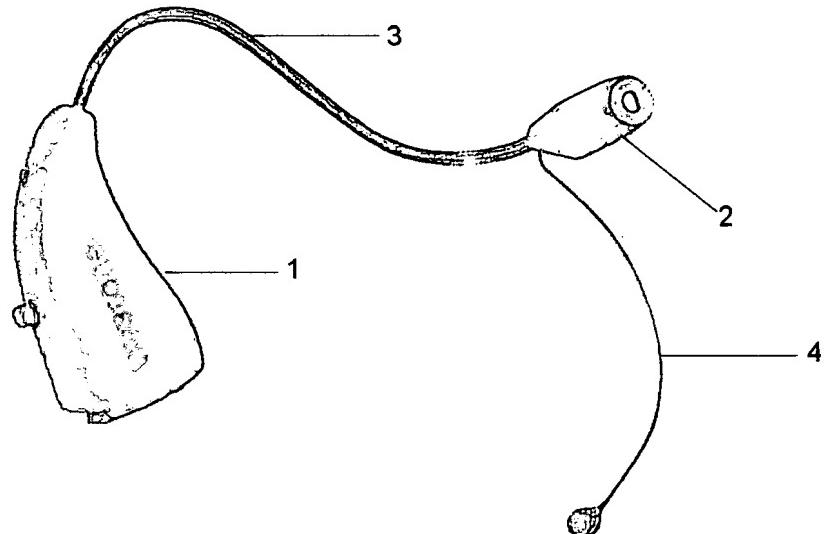
1. I am President of Vivotone Hearing Systems, LLC ("Vivotone"), and assignee of the above-referenced application. I have been intimately involved in the development, manufacture and sale of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal since 2002.
2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:
 - a hearing aid system, comprising:
 - a microphone sampling position located externally of an ear canal of a user,
 - a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal,
 - wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection

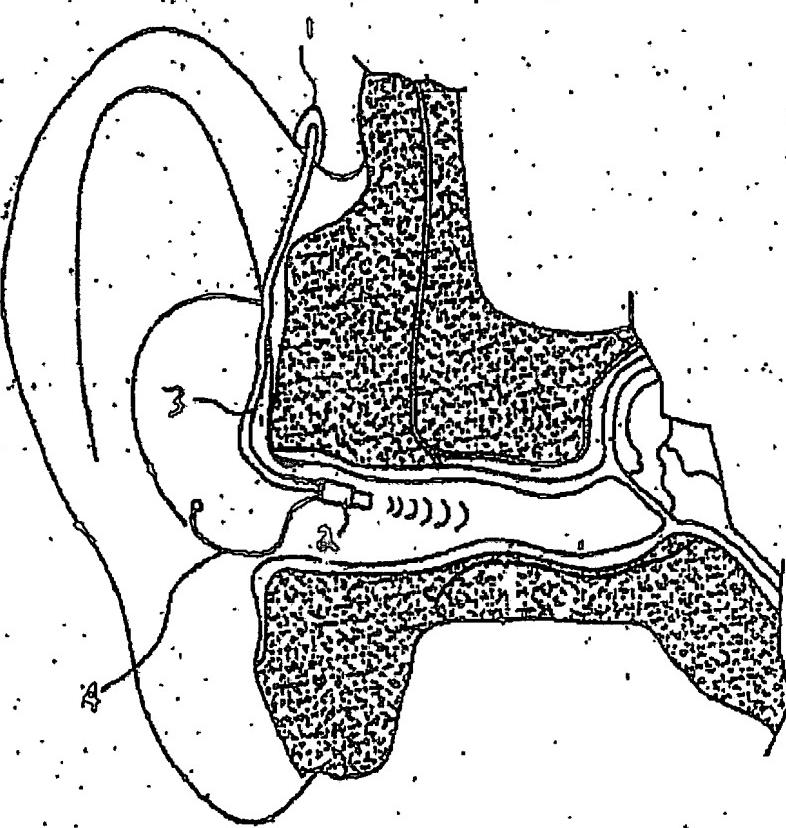
around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration,

wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. The claims of the above-referenced claims correlate with the commercial Vivotone open ear hearing aid system. Reference is made to the following images of the commercial Vivotone device as an aid to review of the following claim chart:





The following claim chart relates aspects of the claimed Vivotone hearing aid to commercialized Vivotone hearing aid to which the above-described commercial success figures above relate. Relevant portions of independent claims (which portions are substantially reproduced in the remaining independent claims) are reproduced below:

A hearing aid, comprising: a microphone sampling position located externally of an ear canal of a user;	The Vivotone hearing aid includes a microphone and microphone port located within the behind-the-ear component (1).
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal;	The receiver (2) comprises a speaker (5) provided within the ear canal in an open ear configuration and is suspended within the ear canal by virtue of the stiffness of the intermediate wire (3) and/or the effect of the concha wire (4).

wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;	The sampled sounds are passed to an amplifier provided in the behind the ear component (1), amplified in accordance with hearing loss programming and are relayed to the speaker (5) via the intermediate wire (3), which is provided around a portion of the external ear into the ear canal opening.
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit	The microphone port and amplifier are both contained within the behind the ear component (1).

The additional aspect of the independent claim 1 is also embodied in the commercial Vivotone device, including the receiver generating about three decibels or below of insertion loss over a portion of human ear audible frequencies.

4. My open ear hearing aid was first commercially launched by Vivotone in the first quarter of 2004, and is embodied in a product designated the "Vivotone Mini", the "Vivotone Standard" or the "Vivotone Dual". At the time of the open ear hearing aid commercial launch, Vivotone, as a small startup company whose product line consisted solely of the open ear hearing aid product, did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivotone did not engage in any television or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal. Notwithstanding the lack of name recognition and advertising, Vivotone's open ear hearing aid has achieved a high degree of commercial success. Sales were generated principally by word of mouth by audiologists, and by side-by-side demonstrations of Vivotone's open ear hearing aid system with other hearing aids. As may be seen from the sales charts at Exhibit 1 of my September 13, 2006 Declaration, domestic unit sales and domestic net revenues have steadily increased from the first quarter of 2004 until

December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivotone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.¹

5. Various types of hearing aids have been sold marketed and sold for more than 30 years, including completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately adjacent to the ear canal (e.g., in the bowl of the ear). BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing behind the ear and an open tube for directing sound to the ear canal from the speaker housed in the BTE. The Vivotone open ear hearing aid is the FIRST product in those 30 some odd years to incorporate a design that separates the amplification from the speaker, placing the amplification behind the ear (like a BTE device, but unlike the CIC, ITC and ITE devices) while at the same time suspending a small profile speaker in the ear canal to give an open ear configuration. Thus, it took the industry 30 some odd years to create Vivotone's novel open ear hearing aid system configuration, which system minimizes insertion loss and occlusion effect and uses the ear's natural "receiver" to the fullest, mixing natural sounds and amplified sounds in the ear for excellent sound clarity (see the Vivotone Hearing System's brochure at Exhibit 2 of my September 13, 2006 Declaration).

6. While various types of hearing aids have been known for decades, no other company in the hearing aid field was motivated to separate the microphone sampling and amplification from a suspended in-canal speaker (to provide an open ear fitting remote from the BTE microphone and amplifier) until the Vivotone open ear hearing aid in 2004.

¹ However, since the introduction of the Oticon and Hansaton hearing aid products, which as discussed hereafter, constitute copies of our claimed invention, U.S. domestic sales of the Vivotone product have declined.

In my opinion, this fact alone indicates that it was not obvious to provide for such a novel open ear configuration in a hearing aid system.

7. Our open ear hearing aid system resolves the biggest problems that hearing aid wearers experienced prior to the introduction of the Vivotone hearing aid solution: occlusion, insertion loss, feedback and resonance effects (depending on the type of hearing aid used). Occlusion is the “head in the barrel” effect created when the hearing aid wearer speaks or chews. Feedback is the whistling sound experienced when a patient places a telephone near the ear or other structure. Feedback is similar to the whistling sometimes heard in an auditorium when the microphone is too close to the speaker. Further, BTE devices feeding sound to the ear canal via a sound tube suffer from resonance effects. Vivotone revolutionized hearing aids by developing a product that eliminates the *long felt need* with regard to each of these annoyances. That is, Vivotone enhances hearing while enabling the wearer to enjoy normal speaking, eating or telephone conversation without interference.

8. The reason that Vivotone hearing aids are able to provide these benefits is its unique design. Vivotone’s microphone and amplifier are housed in a small plastic case located behind the ear. Unlike other hearing aids, Vivotone delivers sound from the microphone port in the BTE electronically to its speaker in the open ear canal. The speaker is small enough to allow the ear canal to remain open, and therefore, is non-occluding. This revolutionary approach has advanced the acceptance of hearing aids significantly. As noted, prior to Vivotone, hearing aids either occluded the ear canal or transmitted sound from a speaker located behind the ear to the ear canal through a plastic tube. These designs cause either occlusion or insertion loss or distortion or lack of clarity. Vivotone’s open ear speaker allows the patient’s residual natural sound to combine with the enhanced hearing provided by Vivotone’s processor, giving crisp, clear sound to the patient.

9. I noted in my Declaration of September 13, 2006 that Oticon introduced the “Delta” hearing aid product in February, 2006 and that Hansaton announced the “Free

Soundmanager" hearing aid in March, 2006. Both of these companies are direct competitors of Vivotone. These companies copied our open ear hearing aid invention and aggressively marketed and highlighted the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

10. On October 17, 2006, Siemens Audiologische Technik, GmbH ("Siemens") announced its own RIC ("Receiver in the Canal") hearing aid, called the "CENTRA Active", which is to be released in the beginning of 2007. *See* the Siemens press release at Exhibit 1, attached hereto. Siemens is also a direct competitor of Vivotone and is currently at least the second largest hearing aid manufacturer in the world (my understanding is that until recently, Siemens was the largest). As described below, we believe that the CENTRA Active also copies our open ear hearing aid invention; and the Siemens marketing literature related to the CENTRA Active continually and openly highlights our open ear hearing aid invention as a significant advance in the hearing aid field. More than that, Siemens is using its marketing literature in conjunction with its well known name in the hearing aid industry for its open ear CENTRA Active hearing aid.

11. Exhibit 1, Siemens' October 17, 2006 press release, page 1, describes the CENTRA Active as "the first hearing instrument for that 'best ager'". The release also highlights the RIC aspect by stating, "Since the receiver is no longer within the behind-the-ear (BTE) unit, but inside the canal – and connected to the BTE via thin tubing – the BTE type is particularly small, light, and inconspicuous." The release further states, on page 2, "This so-called receiver-in-the-canal (RIC) technology makes for particularly small and light models with pleasing cosmetics."

12. Siemens' CENTRA Active brochure is provided at Exhibit 2. The CENTRA Active device is described on page 1 as being "Made for active living." The illustration includes (ignoring the tennis racket image) a BTE connected to a receiver that is suspended within the ear canal of a user. Page 3 of the brochure describes the CENTRA Active as "a new kind of Receiver-In-Canal (RIC) system." Page 5 of the brochure

describe the aspects of the hearing aid, including the casing (A), the receiver unit (C) and the dome tip (D on the left image and E on the right image). The dome tip is described on page 6 as being an “occlusion-free dome” (used to suspend the receiver in the ear canal). The design is described as “innovative” and “discreet” on page 18. The receiver is described as being “virtually invisible.” . Page 21 indicates that “CENTRA Active lets wearers live life to the fullest” and that “it is precisely the kind of innovative solution active wearers with mild to severe hearing loss are looking for.”

As is clear from the images of CENTRA Active and from the lauded language in its marketing (e.g., “innovative, discreet design”), the CENTRA Active is very similar to the Oticon Delta, the Hansaton Free Soundmanager and our Vivotone hearing aids (particularly with regard to a behind the ear unit housing an amplifier and a microphone, which is connected via an electrical wire to an open ear speaker suspended within the ear canal).

We have obviously not tested the CENTRA Active; however, review of the images of the device reveal that the device is remarkably similar to both the Oticon Delta and the Vivotone hearing aids. Accordingly, due to the apparent similarities of the Hansaton Free with the Oticon Delta and the Vivotone hearing aids, we expect that the properties of the device will be similar.

Accordingly, we expect that the CENTRA Active is embodied by independent claim 1 of the Vivotone open ear hearing aid system for which a patent was applied for more than three years prior to the announcement of the CENTRA Active and for which the Vivotone product was commercially available more than three years prior to the planned release of the CENTRA Active. We believe this to be clear evidence of copying in the industry, and as will be described below, clear evidence of laudatory remarks of our novel open ear aspects by competitors that have copied us in the marketplace.

13. In addition to my belief that Siemens copied our open ear hearing aid system innovation, it is significant that the announcement and brochure of the new CENTRA Active includes laudatory statements regarding the benefits of the claimed design (that is, a BTE combined with an open ear receiver) thus supporting my contention that our open

ear hearing aid system innovation is nonobvious. I have yellow highlighted such laudatory statements in each of Exhibits 1 and 2 which state, for example:

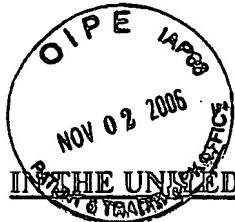
<u>Exhibit</u>	<u>Statement</u>
1	p.1 "Since the receiver is no longer within the behind-the-ear (BTE) unit, but inside the canal – and connected to the BTE component via thin tubing – the BTE type is particularly small, light and inconspicuous." (bold)
	p.2 "This so-called receiver-in-the-canal (RIC) technology makes for particularly small and light models with pleasing cosmetics"
2	p.1 "Made for active living." (bold)
	p.3 "That's why Siemens created a new kind of Receiver-in-Canal (RIC) system." (large font)
	p.6 "occlusion free domes"
	p.18 "Innovative, discreet design"
	"Virtually invisible receiver unit"
	p.21 "Domes ... with occlusion-free fitting." "CENTRA Active lets wearers live life to the fullest. It is precisely the kind of innovative solution active wearers with mild to severe hearing loss are looking for."

14. As is clear from my description in Paragraphs 11-13 above, Siemens has repeatedly and continuously described our claimed hearing system as a "new" and "innovative" in the field of hearing aids. These laudatory statements exist despite the fact that various different types of hearing aids, including BTE, CIC, ITE and ITC hearing aids, have been known for decades prior to introduction of the Vivatone open ear hearing aid system.

I declare under penalty of perjury that the foregoing is true and correct.


Leon Hirsch

October 31, 2006



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004)
For: HEARING AID SYSTEM) Confirmation No. 8615

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

EXHIBITS FOR DECLARATION UNDER 37 CFR 1.132

Sir:

Please find the attached Exhibits for the 37 C.F.R. 1.132 Declaration of Leon Hirsch, dated October 31, 2006 and filed on November 2, 2006.

EXHIBIT TABLE OF CONTENTS

The attached Exhibit includes the following:

EXHIBIT 1: Siemens Press Release Dated October 17, 2006; and

EXHIBIT 2: Siemens CENTRA Active brochure.

If there are any charges with respect to this submission or otherwise, please charge them to Deposit Account 06-1130, maintained by the Applicant's attorneys.

Respectfully submitted,

CANTOR COLBURN LLP

By: H.M. Bedingfield

H.M. Bedingfield
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Telephone (860) 286-2929
Facsimile (860) 286-0115
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November 2, 2006

EXHIBIT 1

For the trade press

Erlangen, October 17, 2006

Siemens is showcasing the first hearing instrument for that "best ager" generation

A world's first: Moisture resistant and, when fully recharged, ready to handle even those long days

Centra Active, the latest solution in Siemens hearing instruments, is the first model specifically focused on the needs of the active older generation, a demographic segment steadily increasing worldwide. Since the receiver is no longer within the behind-the-ear (BTE) unit, but inside the canal – and connected to the BTE component via thin tubing – the BTE type is particularly small, light, and inconspicuous. Nevertheless, Centra Active offers all the breakthrough technology you have come to expect from the Centra portfolio of hearing instruments, such as "SoundSmoothing" with its attenuation of transient noise and "e2e wireless" technology. And through its unique "DataLearning" feature, the system will adapt itself to the individual preferences of its wearer. And that is not all: **Centra Active is the first moisture resistant hearing instrument worldwide which, when recharged overnight, will last the entire day.**

They come by many names. They are known as "best agers," "young at heart," "golden oldies," or "baby boomers." They go jogging, mountaineering or sailing, play golf and tennis, and love mountain biking. And even when it comes to their age they do not fit the mold. Sometimes they are called "50 plus" and at other times "60 plus." But it always boils down to the same thing: In the developed countries there is a burgeoning group of

1 / 3

active discerning consumers who are enjoying the second half of their life. And it is precisely this group of people whom Siemens had in mind when it developed its new Centra Active model.

Contrary to most conventional behind-the-ear (BTE) instruments, in the Centra Active the receiver is placed within the canal. This so-called receiver-in-the-canal (RIC) technology makes for particularly small and light models with pleasing cosmetics. Furthermore, this instrument comes not only in the standard colours of beige, granite, grey and brown, but also in black, pearl white and silver, as well as in typical hair colours.

However, its highlight is the advanced technology, especially with the moisture resistance and the cutting-edge battery technology. To date, sweat and moisture have always been regarded as the "enemies" of hearing instruments since they might interfere with their sensitive electronics. Active people, particularly those with demanding leisure activities, quite often had to put up with certain limitations. But Centra Active has relegated all that to the past because the housing is sealed by nano coating: sweat simply rolls off, while dust and dirt do not stick. In addition, the sensitive microphones are protected against moisture, rain, and splashes by an easily replaced cover. It contains a Gore membrane which is permeable to sound, but not wind and water. And the "C-Guard" membrane protects the receiver within the canal against dirt, sweat, and cerumen.

The new rechargeable battery technology is extremely user friendly. It makes changing batteries a thing of the past – just recharge the instrument overnight and it will last all day. Simply place the Centra Active into the fully automated charger. Once it is fully recharged (five hours at most) the unit will turn off automatically. Thus, the hearing instruments cannot be overcharged and will always be ready for action.

Here is a quick summary of the other technological highlights:

- "SoundSmoothing" complements present techniques for amplifying speech and attenuates transient noise exactly in those situations which often presented

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problems in the past. Such examples of transient noise would be the clattering of silverware at mealtime, the clacking of high-heels on a wooden floor, or the bang of a closing door.

- "DataLearning" will let Centra Active adapt itself to the volume preferences of its wearer based on his/her personal needs and individual settings in everyday situations.
- In binaural solutions, "e2e wireless" lets two hearing instruments communicate for proper balancing at all times. This not only improves speech recognition and sound quality significantly, but directional hearing and precise position fixing of noise as well.
- Complemented by the additional advances in wind noise reduction and adaptive feedback cancellation, there are almost no applications too tough for the Centra Active to handle.

The new Centra Active will be marketed the beginning of 2007.

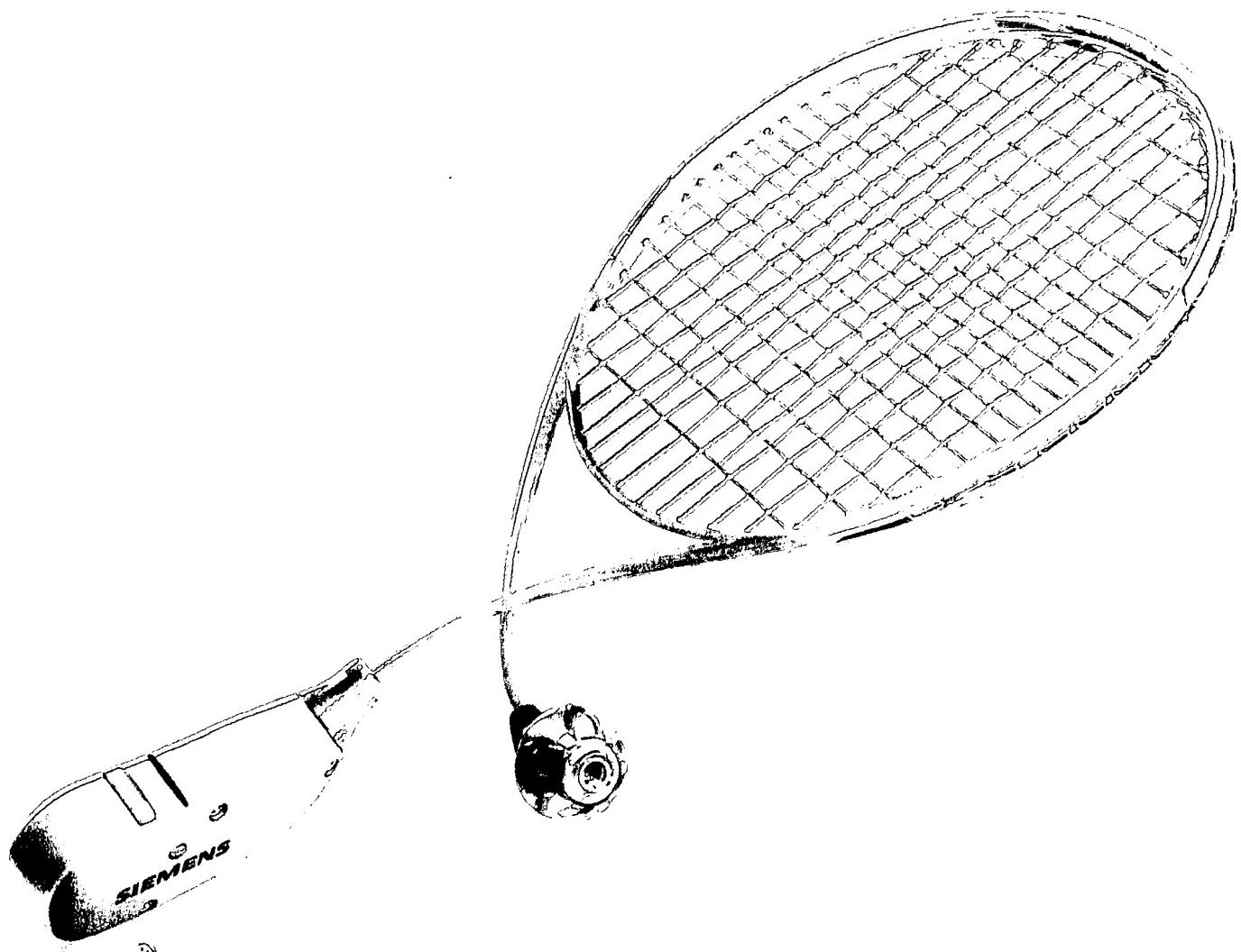
Siemens Medical Solutions is one of the world's largest suppliers to the healthcare industry. The company is known for bringing together innovative medical technologies, healthcare information systems, management consulting, and support services, to help customers achieve tangible, sustainable, clinical and financial outcomes. From imaging systems for diagnosis, to therapy equipment for treatment, to patient monitors to hearing instruments and beyond, Siemens innovations contribute to the health and well-being of people across the globe, while improving operational efficiencies and optimising workflow in hospitals, clinics, home health agencies, and doctors' offices. Employing approximately 33.000 people worldwide and operating in more than 120 countries, Siemens Medical Solutions reported sales of 7.6 billion EUR, orders of 8.6 billion EUR and group profit of 1 billion EUR for fiscal 2005. Further information can be found under: <http://www.siemens.com/medical>

3 / 3

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EXHIBIT 2

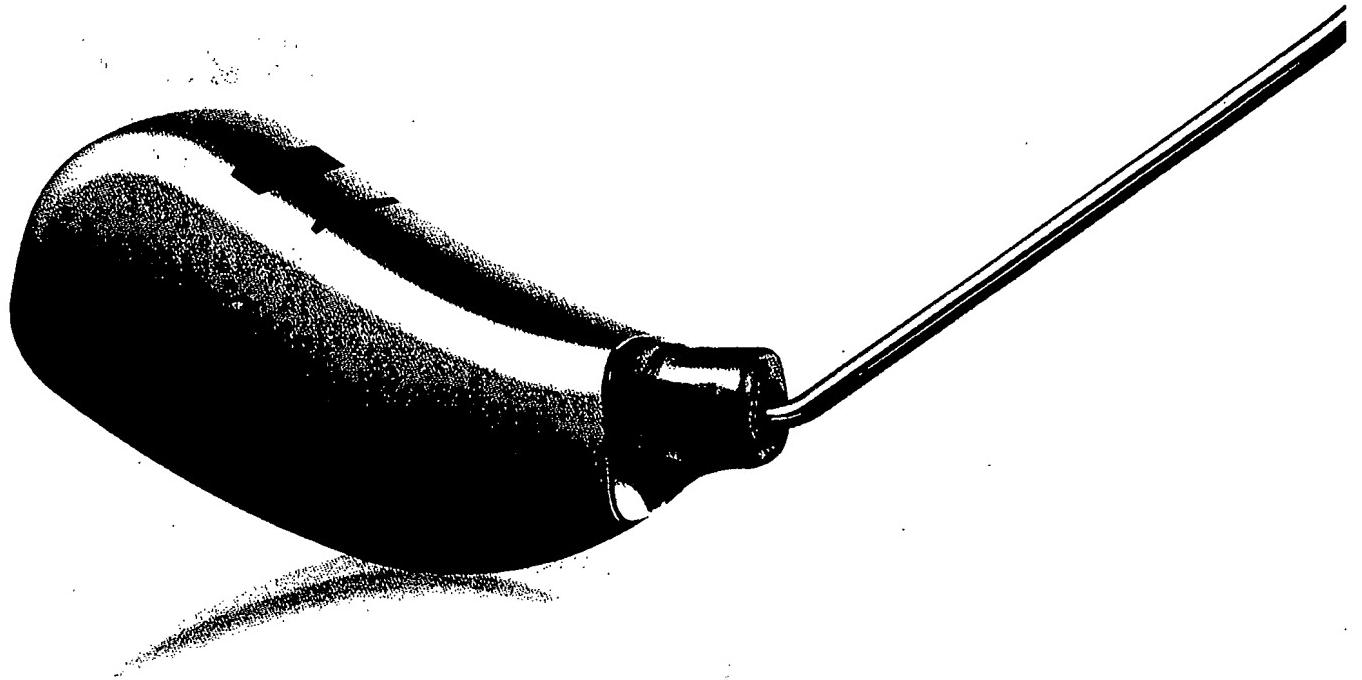


CENTRA Active

Made for active living.

www.siemens.com/hearing

SIEMENS

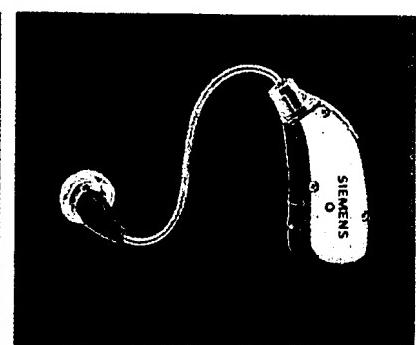
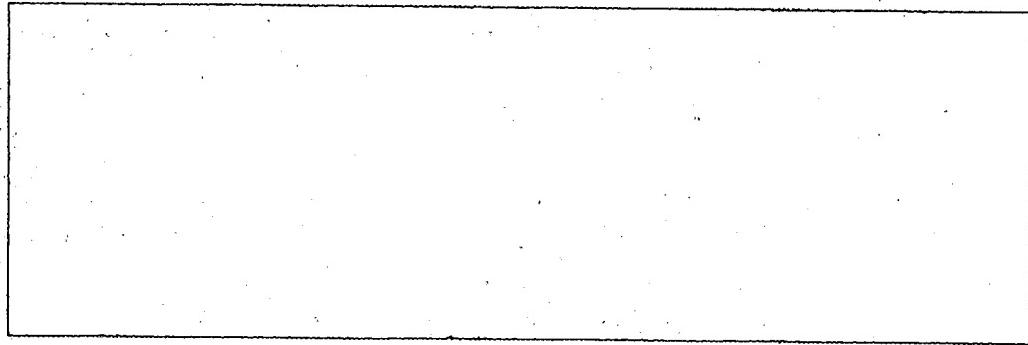




You see them at the gym. On the golf course. Hiking in the woods.

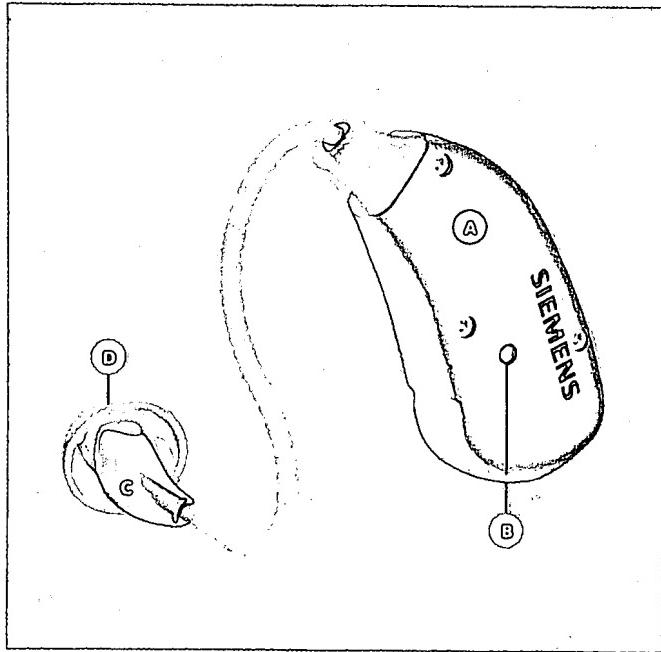
Enjoying life to the fullest. They're today's generation of hearing instrument wearers. And they're more active than ever. That's

why Siemens created a new kind of Receiver-in-Canal (RIC) system called CENTRA Active™. It's everything today's wearers want in a hearing system. Simple to fit and easy to wear, CENTRA Active is water-resistant, rechargeable, and offers unrivaled hearing performance. For active people, it's central to what really matters.



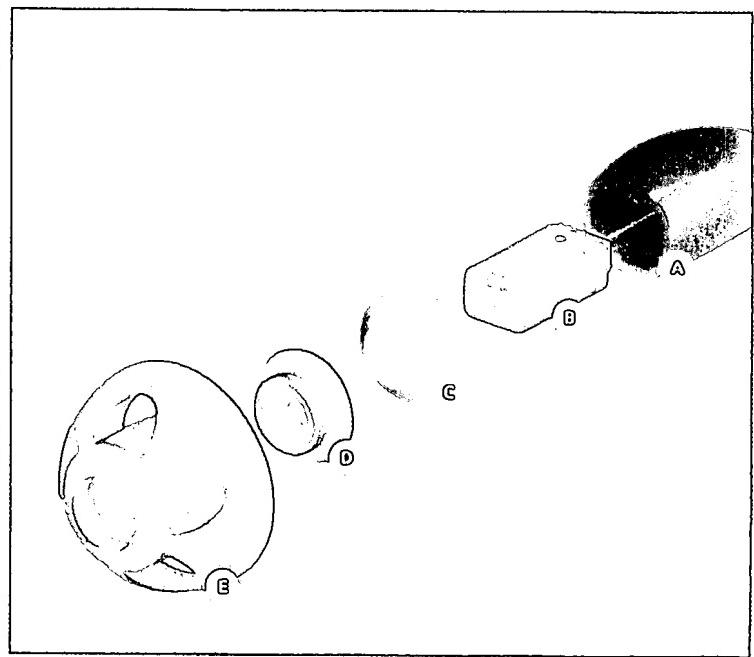
CENTRA Active is the ideal RIC system for a growing number of wearers, offering a level of comfort, ruggedness, and hearing performance no other hearing solution can match.

CENTRA Active at a glance.



CENTRA Active is the only RIC that offers advanced CENTRA technology with SoundSmoothing, DataLearning, and e2e wireless. Its exclusive nanocoated casing and GORE® clip-on microphone cover repel water and prevent moisture and debris from leaking into the instrument.

- A. Casing
- B. Charging contact
- C. Receiver unit
- D. Dome



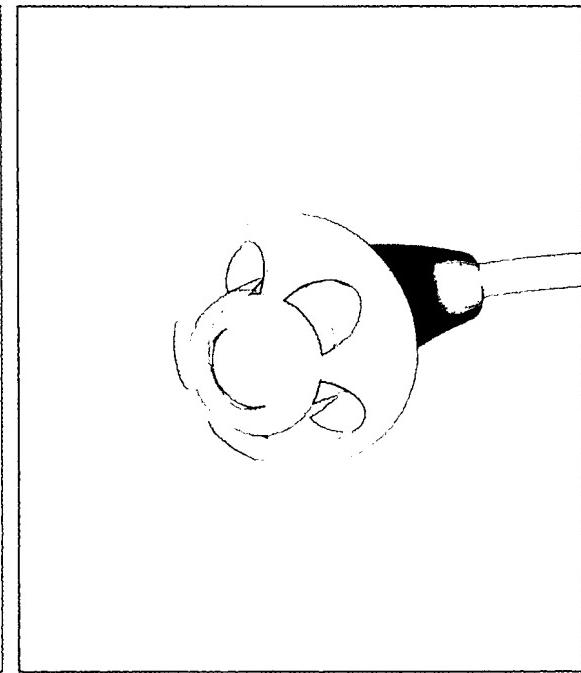
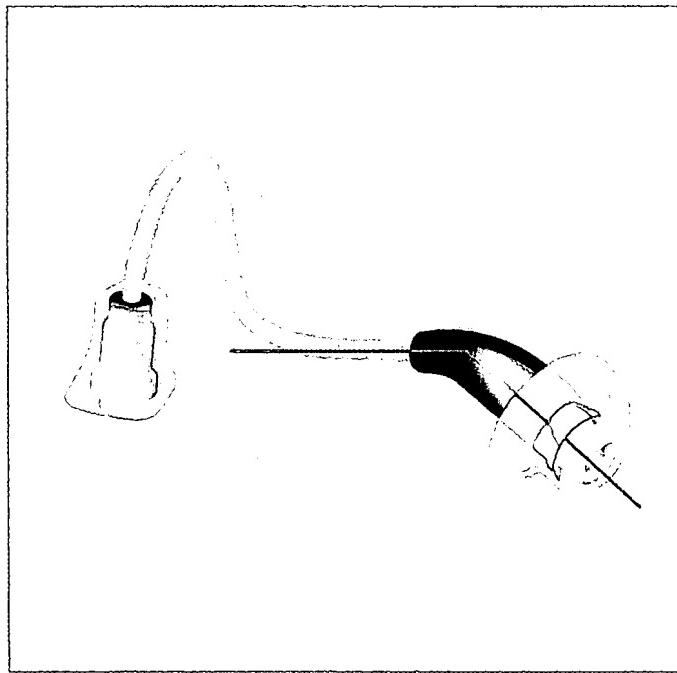
The receiver unit is comfortable, virtually invisible, and available in different lengths. It plugs easily into the body of the instrument with a simple yet secure turn-and-click connection. This exploded view of the receiver unit and dome shows their internal components.

Receiver Unit

- A. Receiver housing
- B. Receiver
- C. Receiver spout

Dome

- D. C-Guard™
- E. Dome tip



Unlike other devices, CENTRA Active's receiver unit is ergonomically designed for optimum placement in the ear canal.

CENTRA Active's occlusion-free domes are available in a wide range of sizes to fit all ear canals.

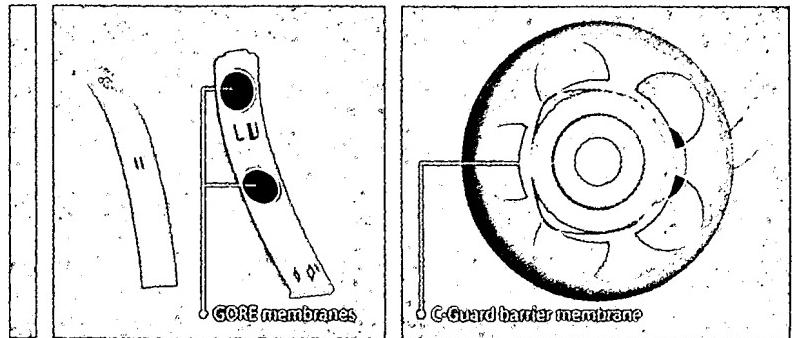
A new standard in RIC performance.

Using wearer-centered engineering, Siemens created a new kind of Receiver-in-Canal instrument, ideal for active wearers with mild to severe hearing loss.

Until now, the chief advantage of RIC systems was their small size and cosmetic appeal. With CENTRA Active, Siemens takes the RIC approach to a whole new level. It's not only small, easy to wear, and cosmetically appealing. It offers a level of comfort and hearing performance no other RIC system can match.

Superior ergonomics and hearing technology. Unlike other RIC designs, CENTRA Active features an ergonomically shaped receiver unit specially designed for optimum placement in the ear canal. It's comfortable, virtually invisible, and available in different lengths for a customized fit. What's more, CENTRA Active's rounded ergonomic shape supports directional technology in the smallest possible size for better hearing in noisy environments. CENTRA Active is also the only RIC that offers advanced CENTRA technology with SoundSmoothing™, DataLearning™, and e2e wireless™ for unmatched hearing performance.

Easy living, fast fitting. CENTRA Active is made for easy living. Thanks to its array of automated features, there are no controls to fuss with. It's easy to fit as well. In fact, wearers can be tested and fit with CENTRA Active in just one appointment. The receiver unit plugs into the body of the instrument with a simple yet secure turn-and-click connection, and the occlusion-free domes are available in a wide range of sizes to fit all ear canals. Wearers can also choose from an expanded array of new colors to match skin and hair tones.



CENTRA Active features a clip-on microphone cover with an integrated GORE membrane that protects it from moisture. A C-Guard barrier membrane for the dome provides maximum protection against cerumen and humidity.

Don't sweat it.

A robust, water-resistant design ideal for people on the go.

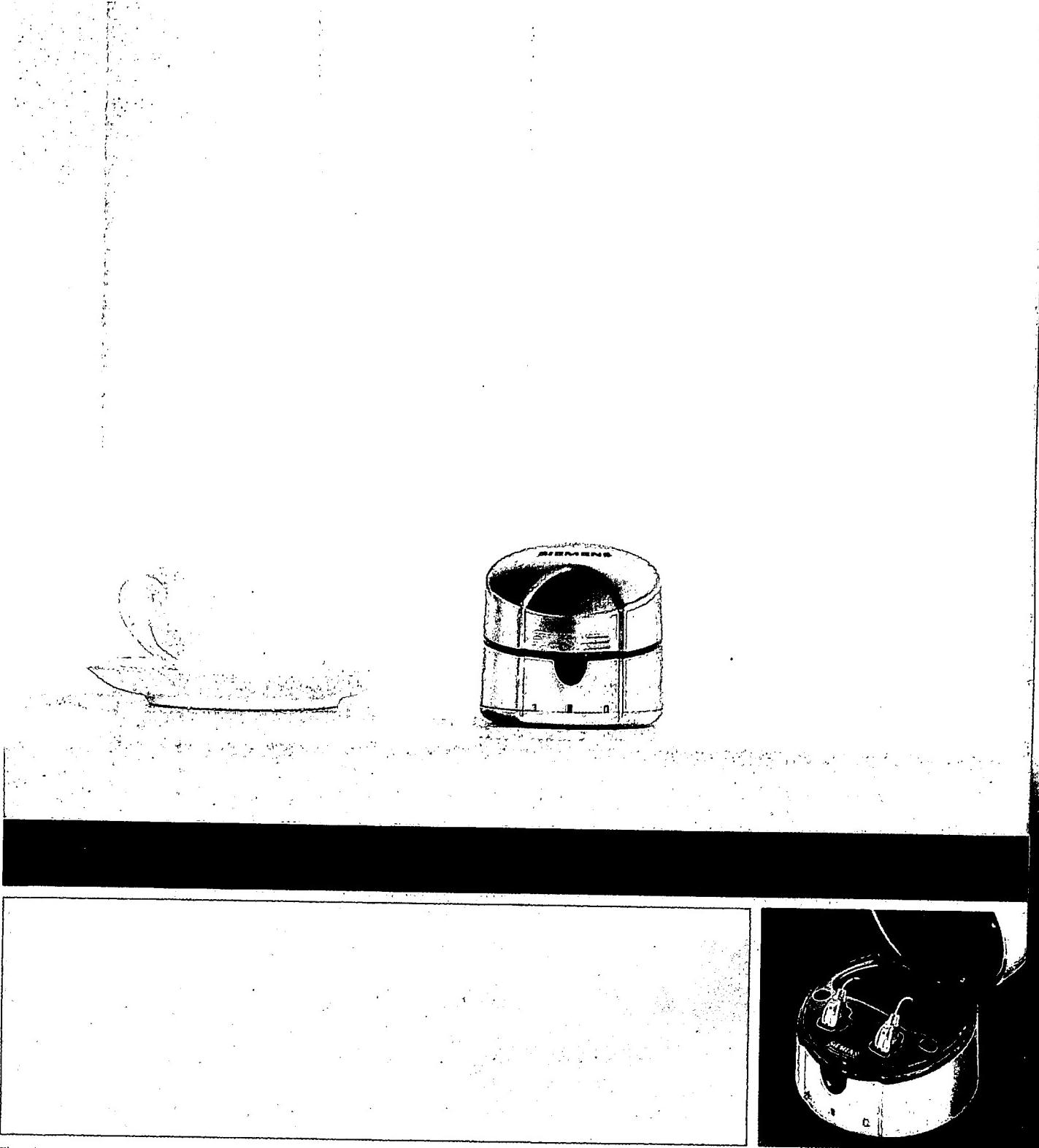
With other hearing solutions, active wearers have problems doing things they enjoy, whether it's digging in the garden, hiking in the mountains or just going for a walk on a warm summer day. They worry that sweat and moisture may damage their hearing instruments.

CENTRA Active wearers don't have to worry about working up a sweat. This unique hearing solution offers an array of innovations that make it resistant to sweat, moisture, and humidity. Its clip-on microphone cover features an integrated GORE membrane that protects it from moisture. The clip-on cover not only repels perspiration, water, and other liquids, but also provides an effective barrier against dust, dirt, and microparticles. It can be easily replaced by the wearer and offers a level of moisture

protection not available in any other hearing solution. In addition, CENTRA Active's casing features nanocoating, a proprietary hydrophobic technology for hearing instruments from Siemens that actually repels water, and prevents moisture and debris from leaking into the instrument. Nanocoating minimizes the chances of corrosion and malfunction, and greatly enhances reliability and performance. And only Siemens has it.

Moisture protection also extends to CENTRA Active's dome, thanks to C-Guard technology. C-Guard's barrier membrane offers maximum protection against cerumen and humidity for months at a time, and can easily be replaced by the wearer.





The charger selects the recharge time automatically – approximately five hours for a fully-drained rechargeable battery.

Bye bye batteries.

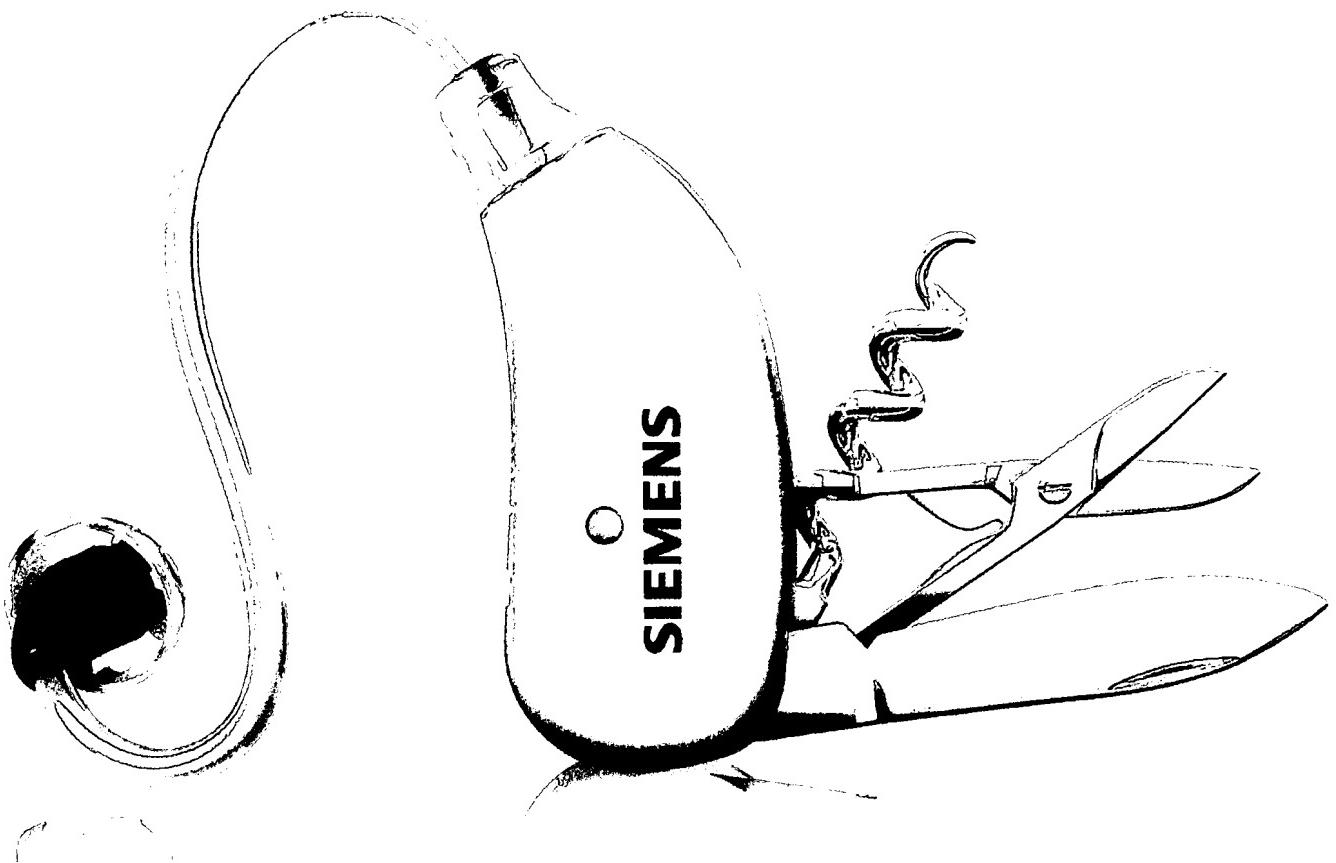
With CENTRA Active's easy-to-use charger, the instruments work all day on a single night's charge.

Imagine the freedom of not having to worry about batteries. Imagine never having to waste valuable counseling time clarifying the confusion that batteries pose for some wearers. And imagine feeling confident that when clients with dexterity problems leave your office they won't have any handling issues. That's the freedom and convenience CENTRA Active's rechargeable feature offers you and your clients. In fact, it's the only hearing instrument of its kind that's rechargeable.

The stylish, intelligent CENTRA Active charger is simple to operate. Just place the instruments in the charger – up to two instruments at a time. They don't even have to be turned off because the charger does that automatically. It also charges the instruments "intelligently," indicating if the wearer has attempted to charge the instruments with non-rechargeable batteries, or has reversed the polarity of the batteries in the instruments. After just five hours of charging, the charger shuts itself off and the hearing instruments are ready to run a full active day. For even greater convenience, CENTRA Active will also run on regular size 13 batteries.

Technology that's
anything.

Engineered to offer unsurpassed hearing performance in any environment, CENTRA Active provides the most natural, personal, and comfortable hearing experience possible thanks to breakthrough technologies like SoundSmoothing, DataLearning, and e2e wireless. And a complete array of the most advanced, automated hearing instrument features.



SoundSmoothing

SoundSmoothing is the first and only sound suppression system that automatically distinguishes transient noises from speech. It provides world-class wearer comfort by targeting and suppressing impulsive non-speech sounds that traditional noise reduction systems cannot effectively process – like rustling paper, clanging dishes, and breaking glass – while leaving speech signals intact.

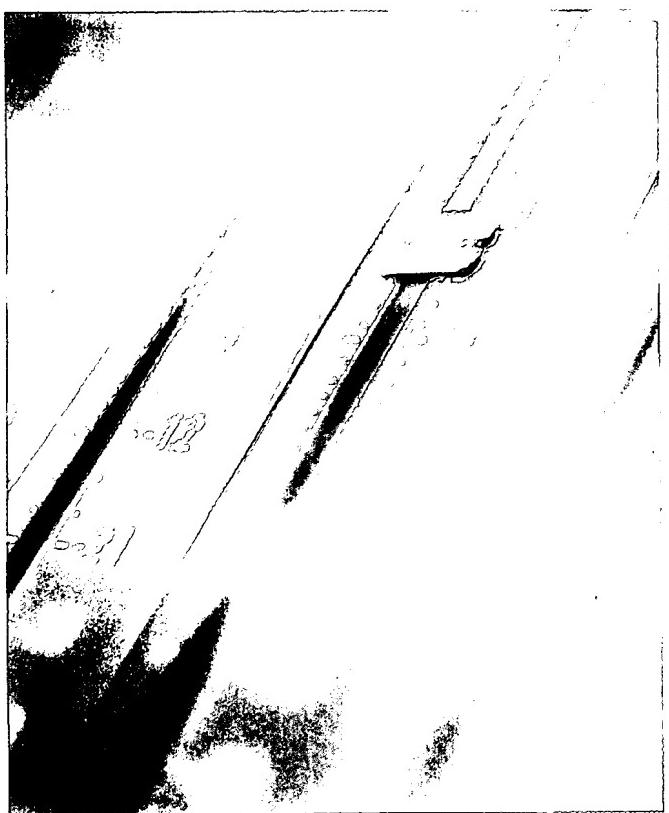
SoundSmoothing also minimizes wearer fatigue and can increase wearing time. In fact, research shows that most hearing instrument wearers prefer SoundSmoothing in situations with transient noise.



DataLearning

Unlike conventional data logging technologies that simply collect data, CENTRA Active's unique DataLearning technology learns the wearer's volume preferences for each program and automatically adjusts the instruments to these preferences for optimal hearing in every hearing environment.

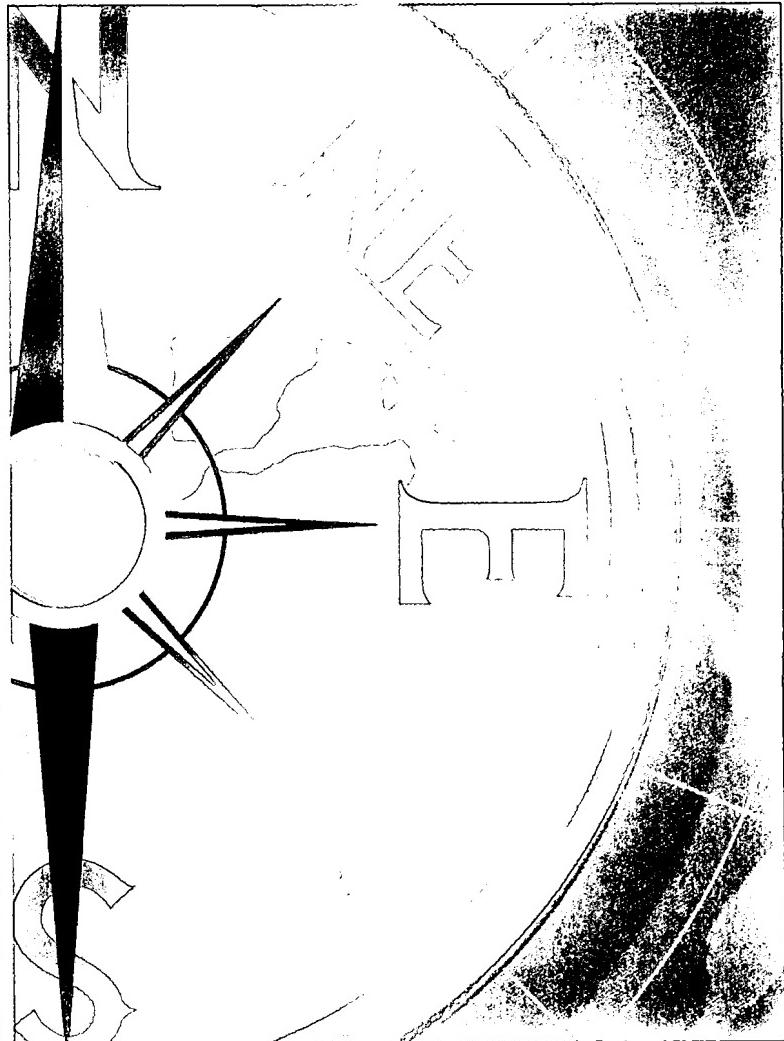
As a result, DataLearning minimizes the long-term need for wearer adjustments, and provides better comfort and performance. In fact, it virtually eliminates the need for volume control changes after one week. Studies show that this learning volume control feature is preferred by wearers. It not only optimizes loudness, but also subjective speech understanding and sound quality when compared to instruments with conventional volume control.



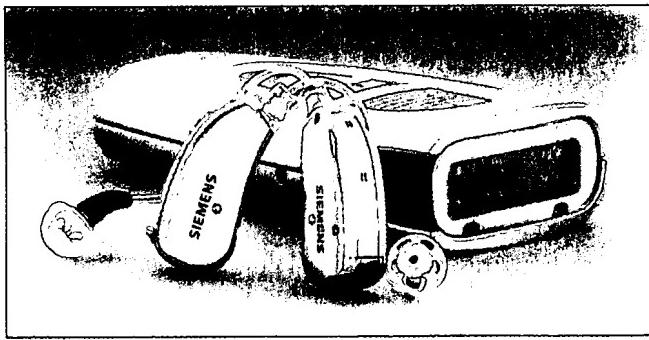
e2e wireless

CENTRA Active's e2e wireless technology synchronizes the signal processing of both hearing instruments in binaural fittings so that they function as one holistic system. It continuously senses the listening environment and automatically aligns selected core digital signal processing. e2e wireless also ensures that volume level and listening programs are always in sync.

Working in concert with CENTRA Active's directional microphones, e2e wireless offers the best localization capability of any hearing system and improves the localization of sounds up to 40%.



The optional ePocket remote control gives wearers easy, finger-tip control over virtually all instrument functions.



ePocket remote control. e2e wireless technology enables the use of an optional ePocket™ remote control. This stylish, discreet, and user-friendly remote gives CENTRA Active wearers easy control of volume, access to multiple listening programs, and the ability to check the battery and system settings. ePocket also eliminates the need for physical controls on the instrument – a great cosmetic advantage and a benefit for those with dexterity problems.



Don't even think about it.

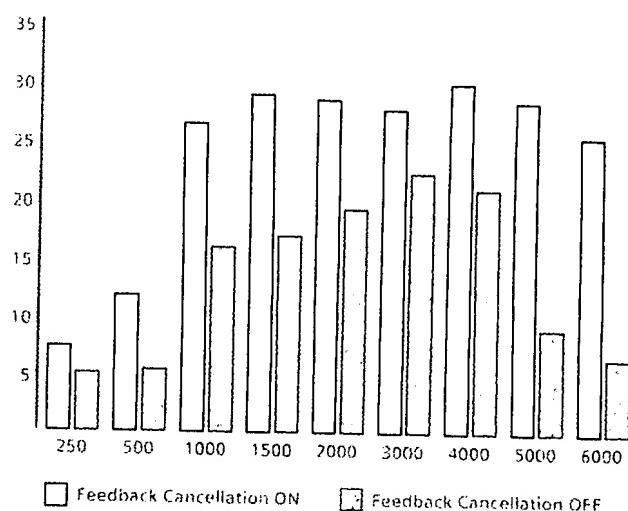
CENTRA Active integrates the most comprehensive array of fully automated hearing instrument features that provide the most wearer-centered hearing experience possible. It requires virtually no wearer intervention for maximum ease of use.

Automatic Feedback Cancellation.

Conventional feedback cancellation systems often identify signals like music or microwave beeps as feedback and create artifacts that are confusing or bothersome to the wearer. The only way to avoid this problem is by turning off the feedback cancellation system or reducing the reaction time of the feedback system.

CENTRA Active is different. It offers the most advanced feedback cancellation system available, featuring a new algorithm with adaptive speed control that automatically selects the optimal adaptation speed to eliminate or reduce feedback and to avoid any artifacts. Specifically, the CENTRA feedback cancellation system provides up to 18 dB additional gain, and reduces or eliminates feedback with virtually no artifacts in any condition.

Feedback Cancellation Effect



Automatic Speech and Noise Management.

Together with SoundSmoothing, CENTRA Active's speech and noise management system is the most automatic and advanced in the industry. It reduces distracting sounds without compromising speech, and provides world-class comfort and sound quality.

Speech Enhancement. CENTRA Active's speech enhancement provides intersyllabic noise reduction, which analyzes speech and noise independently, to reduce the background noise level between the gaps within syllables and words.

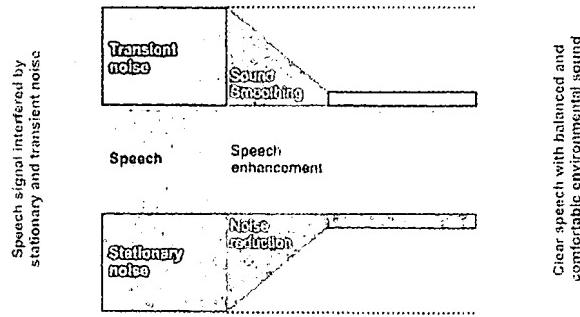
Noise Reduction. The system continuously analyzes the incoming signal and, based on its frequency, amplitude, and depth of modulation determines if it is speech or noise. The system then reduces steady-state noises, like air conditioners, vacuum cleaners, and traffic noise.

True 16-Channel Digital Signal Processing.

CENTRA Active gives the professional access to 8 compression regions and 16 bands for accurate frequency shaping and compression adjustment. This enables optimal use of the wearer's residual dynamic range and a smooth frequency response. It also allows more customization and fitting flexibility than any other product on the market, and delivers excellent sound quality and natural audibility for all sound input levels.

Automatic and Adaptive Directional Microphone System.

CENTRA Active's directional microphone system automatically adapts to the current listening situation and optimizes system settings. It improves speech intelligibility in noisy situations, even in dynamic listening conditions such as busy restaurants, where there may be several competing noise sources. In fact, CENTRA Active's automatic, multichannel adaptive directional microphone system outperforms competitive systems by up to 4 dB.



Clear speech with balanced and comfortable environmental sound

CENTRA Active's automatic Speech and Noise Management System employs various sophisticated signal processing algorithms in an optimum manner. Noise reduction is most efficient for noise only, whereas speech enhancement is used if a mixture of speech and noise is present. SoundSmoothing reduces the annoyance of transient noises whether speech is present or not. And it's all done automatically.

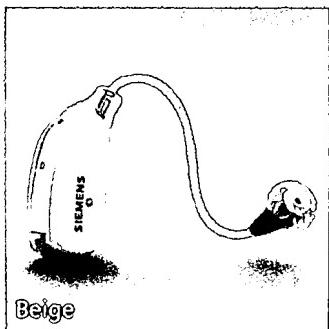
Automatic Reduction of Wind Noise.

CENTRA Active's state-of-the-art wind noise reduction system, eWindScreen, provides marked improvement over other systems and is effective even in strong wind conditions. Using an advanced algorithm, eWindScreen analyzes incoming signals to detect wind noise, then automatically adjusts signal processing to quickly reduce it. The result is a completely automatic solution for wind that enables even your most active clients to enjoy outdoor activities without compromise.

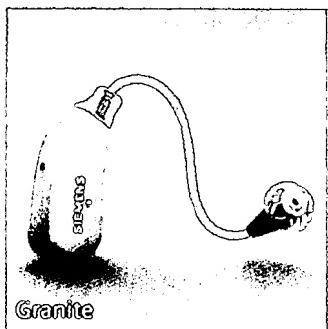
Product information

Instrument Features	Signal Processing Features	Rechargeable Features
Innovative, discreet design available in an array of colors, including hair tones.	SoundSmoothing	Works all day long on a single charge
Virtually invisible receiver unit with secure turn-and-click connection to amplifier, available in three sizes each for left and right sides.	DataLearning	Five hours charge time
Domes with integrated C-Guard technology enable long-lasting operation with occlusion-free fitting. Available in a variety of open and closed sizes.	e2e wireless	Size 13 rechargeable battery
ePocket remote control option for discreet and easy adjustment and access to multiple listening programs.	CENTRA signal processing with 16-channel frequency shaping and compression system	Automatic switch-off when instrument is placed into charger and closed
CENTRA Active charger includes charging cradle, power supply, and two rechargeable batteries (size 13, 30mAh).	Automatic, multichannel adaptive directional microphone system	Two instruments can be charged simultaneously
	Advanced automatic feedback cancellation system with adaptive speed control	Easy-to-understand charger status indicators
	eWindScreen, electronic wind noise reduction system	Safe and easy to use. Recognizes non-rechargeable batteries and notifies wearer via LED status without harming instrument or batteries.
Wearer Features	Special Features	Wearer Features
Maximum Sound Pressure Level (OSPL 90): 108 dB	Water-resistant dome with integrated C-Guard technology for maximum resistance against cerumen and humidity. The dome can be changed by the wearer.	ePocket remote control option gives the wearer access to volume control, program adjustment, and battery status readout.
Peak Gain: 45 dB	Water-resistant clip-on cover for microphones with integrated GORE membrane for superior resistance against sweat and humidity. The clip-on cover can be changed by the wearer.	
	Nanocoated housing repels water, prevents moisture and debris from leaking into the instrument, and minimizes the chances of corrosion and malfunction.	

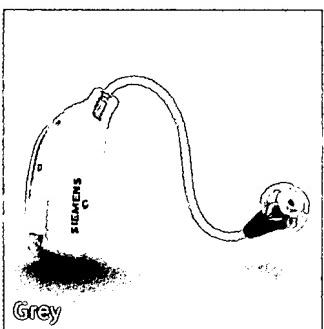
Available Colors (Additional Colors Not Shown)



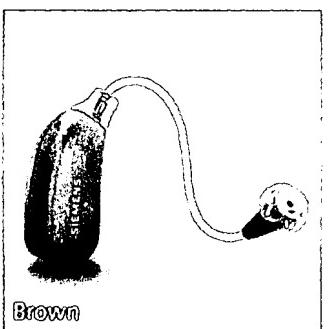
Beige



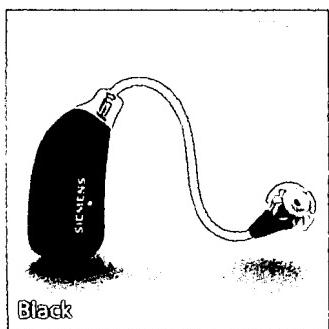
Granite



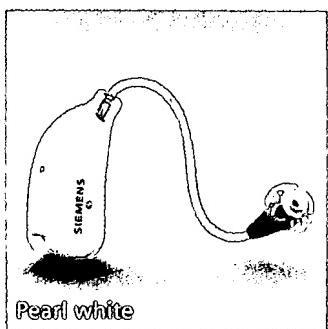
Grey



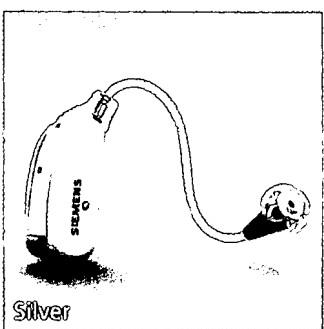
Brown



Black



Pearl white



Silver

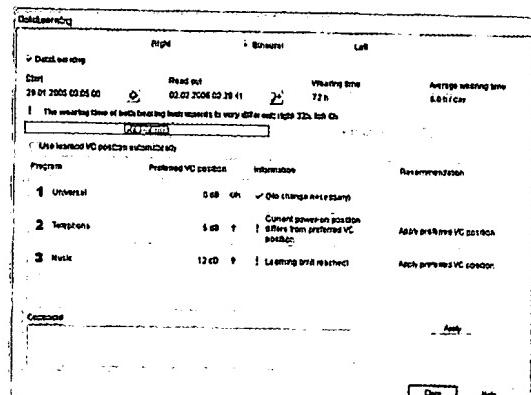
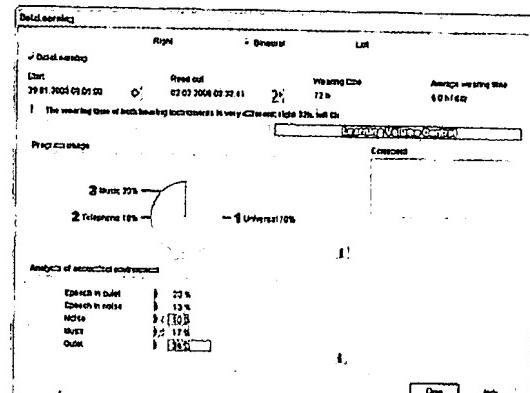
CONNEXX

makes fitting fast and easy.

CONNEXX™ 5 programming software helps streamline your workflow so you can deliver the most accurate, comfortable, and successful fit possible. Developed to fully support CENTRA Active binaural fittings, CONNEXX 5 incorporates exceptional flexibility with the efficiency of a workflow-oriented approach. For binaural fittings, programming features such as Parameter Coupling and Binaural and Program Link simplify the fitting process, so any parameter changes made to one instrument can be automatically applied to the other. In fact, Hearing Care Professionals report that CONNEXX 5 makes the fitting process simpler and more efficient than ever.

DataLearning. With this automated feature, loudness adjustments are made by the system without requiring extra effort on the part of the Hearing Care Professional, as is the case with less sophisticated systems that only log data. DataLearning also enables faster, more precise, and more personalized fitting during follow-up visits by providing objective usage data for fine-tuning and counseling.

DataLearning includes a Learning Volume Control feature with two operational modes. Using CONNEXX 5, you can access either the default mode, where the instrument automatically adopts your client's volume preferences, or the second mode, which lets you apply the learned volume preferences at your discretion.



For over 127 years, Siemens has been dedicated to developing innovative solutions to meet the changing needs of people with hearing loss. CENTRA Active is a perfect expression of that commitment. Water-resistant, rechargeable, easy to wear, and offering unrivaled hearing performance, CENTRA Active lets wearers live life to the fullest. It is precisely the kind of innovative solution active wearers with mild to severe hearing loss are looking for. One you can recommend and fit with confidence.

For those with
better things to do.



The information in this document contains general descriptions of the technical options available, which do not always have to be present in individual cases and are subject to change without prior notice.

The required features should therefore be specified in each individual case at the time of conclusion of the respective contract.

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Order No. A915AT-00028-99C1-7600
Printed in Germany
104300/C7614 WS 10061.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004)
For: HEARING AID SYSTEM) Confirmation No. 8615

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Leon Hirsch declares and says that:

1. I am President of Vivotone Hearing Systems, LLC ("Vivotone"), and assignee of the above-referenced application. I have been intimately involved in the development, manufacture and sale of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal since 2002.

2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:

a hearing aid system, comprising:

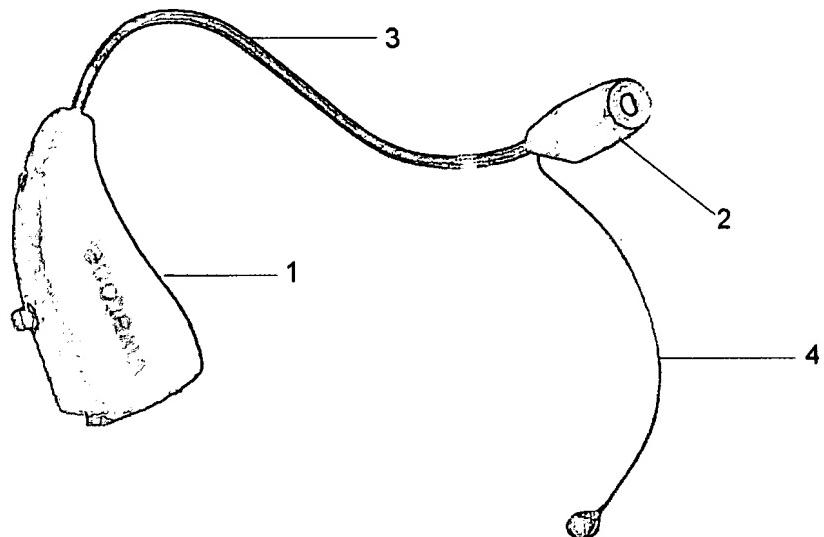
a microphone sampling position located externally of an ear canal of a user,

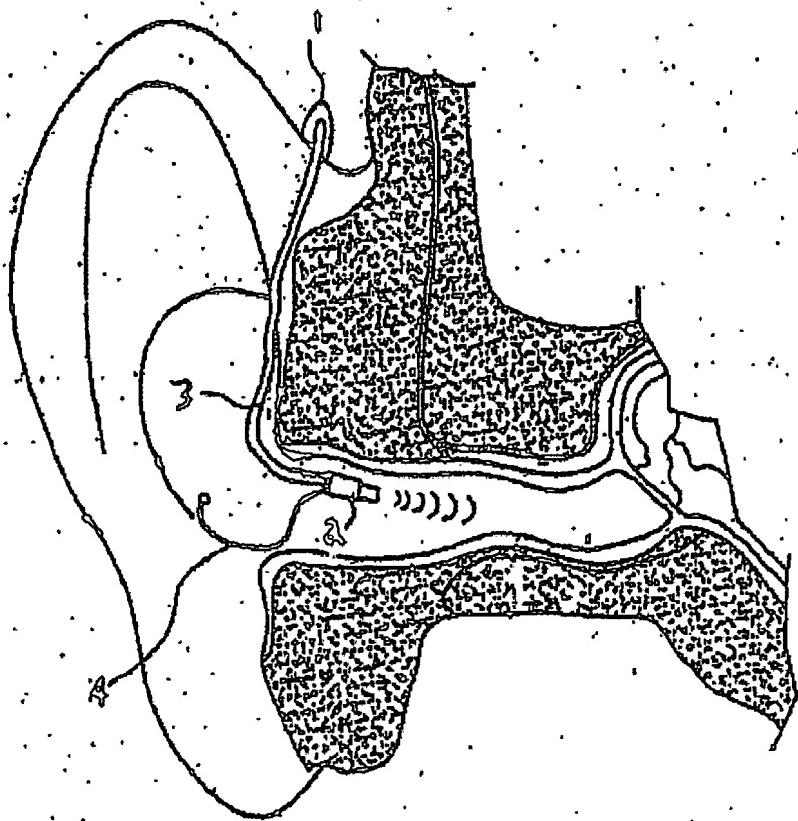
a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through

the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration, wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. As noted in my Declaration of October 31, 2006, the claims of the above-referenced claims correlate with the commercial Vivotone open ear hearing aid system. Reference is made to the following images of the commercial Vivotone device as an aid to review of the following claim chart:





The following claim chart relates aspects of the claimed Vivotone hearing aid to commercialized Vivotone hearing aid to which the above-described commercial success figures above relate. Relevant portions of independent claims (which portions are substantially reproduced in the remaining independent claims) are reproduced below:

A hearing aid, comprising: a microphone sampling position located externally of an ear canal of a user;	The Vivotone hearing aid includes a microphone and microphone port located within the behind-the-ear component (1).
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal;	The receiver (2) comprises a speaker (5) provided within the ear canal in an open ear configuration and is suspended within the ear canal by virtue of the stiffness of the intermediate wire (3) and/or the effect of the concha wire (4).

wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;	The sampled sounds are passed to an amplifier provided in the behind the ear component (1), amplified in accordance with hearing loss programming and are relayed to the speaker (5) via the intermediate wire (3), which is provided around a portion of the external ear into the ear canal opening.
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit	The microphone port and amplifier are both contained within the behind the ear component (1).

The additional aspect of the independent claim 1 is also embodied in the commercial Vivotone device, including the receiver generating about three decibels or below of insertion loss over a portion of human ear audible frequencies.

4. My open ear hearing aid was first commercially launched by Vivotone in the first quarter of 2004, and is embodied in a product designated the “Vivotone Mini”, the “Vivotone Standard” or the “Vivotone Dual”. At the time of the open ear hearing aid commercial launch, Vivotone, as a small startup company whose product line consisted solely of the open ear hearing aid product, did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivotone did not engage in any television or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal. Notwithstanding the lack of name recognition and advertising, Vivotone’s open ear hearing aid has achieved a high degree of commercial success. Sales were generated principally by word of mouth by audiologists, and by side-by-side demonstrations of Vivotone’s open ear hearing aid system with other hearing aids. As may be seen from the sales charts at Exhibit 1 of my September 13, 2006 Declaration, domestic unit sales and

domestic net revenues have steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivotone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.¹

5. Various types of hearing aids have been sold marketed and sold for more than 30 years, including completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately adjacent to the ear canal (e.g., in the bowl of the ear). BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing behind the ear and an open tube for directing sound to the ear canal from the speaker housed in the BTE. The Vivotone open ear hearing aid is the FIRST product in those 30 some odd years to incorporate a design that separates the amplification from the speaker, placing the amplification behind the ear (like a BTE device, but unlike the CIC, ITC and ITE devices) while at the same time suspending a small profile speaker in the ear canal to give an open ear configuration. Thus, it took the industry 30 some odd years to create Vivotone's novel open ear hearing aid system configuration, which system minimizes insertion loss and occlusion effect and uses the ear's natural "receiver" to the fullest, mixing natural sounds and amplified sounds in the ear for excellent sound clarity (see the Vivotone Hearing System's brochure at Exhibit 2 of my September 13, 2006 Declaration).

6. While various types of hearing aids have been known for decades, no other company in the hearing aid field was motivated to separate the microphone sampling and

¹ However, since the introduction of the Oticon and Hansaton hearing aid products, which as discussed hereafter, constitute copies of our claimed invention, U.S. domestic sales of the Vivotone product have declined.

amplification from a suspended in-canal speaker (to provide an open ear fitting remote from the BTE microphone and amplifier) until the Vivotone open ear hearing aid in 2004. In my opinion, this fact alone indicates that it was not obvious to provide for such a novel open ear configuration in a hearing aid system.

7. Our open ear hearing aid system resolves the biggest problems that hearing aid wearers experienced prior to the introduction of the Vivotone hearing aid solution: occlusion, insertion loss, feedback and resonance effects (depending on the type of hearing aid used). Occlusion is the “head in the barrel” effect created when the hearing aid wearer speaks or chews. Feedback is the whistling sound experienced when a patient places a telephone near the ear or other structure. Feedback is similar to the whistling sometimes heard in an auditorium when the microphone is too close to the speaker. Further, BTE devices feeding sound to the ear canal via a sound tube suffer from resonance effects. Vivotone revolutionized hearing aids by developing a product that eliminates the *long felt need* with regard to each of these annoyances. That is, Vivotone enhances hearing while enabling the wearer to enjoy normal speaking, eating or telephone conversation without interference.

8. The reason that Vivotone hearing aids are able to provide these benefits is its unique design. Vivotone’s microphone and amplifier are housed in a small plastic case located behind the ear. Unlike other hearing aids, Vivotone delivers sound from the microphone port in the BTE electronically to its speaker in the open ear canal. The speaker is small enough to allow the ear canal to remain open, and therefore, is non-occluding. This revolutionary approach has advanced the acceptance of hearing aids significantly. As noted, prior to Vivotone, hearing aids either occluded the ear canal or transmitted sound from a speaker located behind the ear to the ear canal through a plastic tube. These designs cause either occlusion or insertion loss or distortion or lack of clarity. Vivotone’s open ear speaker allows the patient’s residual natural sound to combine with the enhanced hearing provided by Vivotone’s processor, giving crisp, clear sound to the patient.

9. I noted in my Declaration of September 13, 2006 that Oticon introduced the “Delta” hearing aid product in February, 2006 and that Hansaton announced the “Free Soundmanager” hearing aid in March, 2006. Both of these companies are direct competitors of Vivotone. These companies copied our open ear hearing aid invention and aggressively marketed and highlighted the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

10. I also noted in my Declaration of October 31, 2006 that on October 17, 2006, Siemens announced its own RIC (“Receiver in the Canal”) hearing aid, called the “CENTRA Active”, which is to be released in the beginning of 2007. This company also copied our open ear hearing aid invention and is aggressively marketing and highlighting the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

11. It has recently come to my attention that Oticon was recently selected as an International CES Best of Innovations 2007 Design and Engineering Award winner for its Delta product (which, as previously discussed, is a copy of the Vivotone’s claimed invention). Exhibit 1, attached hereto, is a November 8 PRNewswire report, which characterizes the Delta as being a “new category.” The report states, “Its revolutionary design is made possible by placing its receiver into the ear canal at the end of a thin, transparent sound wire.” This report calls the Delta hearing aid (which copied our Vivotone hearing aid) “revolutionary” and emphasizes that the marketplace views the configuration as being new.

12. It has also recently come to my attention that a fourth Vivotone competitor, Interton Horgerate, GmbH, recently announced a new RITE (Receiver in the Ear) product, called Shape. Exhibit 2 illustrates the new Interton Shape product alongside the Oticon Delta, the Hansaton Free, the Siemens Centra Active, and our own Vivotone hearing aid. Vivotone’s configuration is being copied over and over again by our major

competitors. Like the others, the Interton Shape includes the BTE component with hearing aid electronics, a receiver in the ear in an open ear fitting, and a thin wire connecting the open ear receiver to the rest of the electronics in the BTE.

13. The Interton advertising also continually characterizes its configuration (copied from Vivotone's configuration) as innovative and otherwise lauds the product. Exhibits 3-5 provides advertising literature for Interton's Shape hearing aid (just as the previously submitted Exhibits showed such literature for Oticon, Hansaton, and Siemens).

Reference will be made to selections from Exhibits 3-5 immediately below:

Referring to Exhibit 3, the advertisement includes on its front page a large heading "**You will hear the difference**". Page 2 does the same, with an image of the product and images of a coat hanger turning into a cymbal. Page 3 goes on to indicate that the Shape is "**A new dimension in hearing comfort**". Page 4 overtly touts the configuration by stating:

The secret of Shape – One solution, two units

With Shape, INTERTON is the first German company to place the receiver (speaker) in the ear canal while the sound processor is worn behind the ear. The result: a highly effective hearing system that provides a much richer sound experience.

The speaker is positioned in the ear canal. The speaker is positioned in the ear canal, while the sound processor sits behind the ear. The units are connected by an invisible tube. By placing the speaker in the ear canal, it is closer to the drum than traditional hearing aids. This unique configuration makes excellent sound quality and cosmetic discretion possible.

Shape – get all the advantages of in-the-ear solution (ITE's) and behind-the-ear solution (BTE's). Because all advantages are combined, Shape offers many benefits. If you are an experienced hearing aid wearer, you are familiar with the advantages and disadvantages of different hearing aids.

With Shape, there are no compromises – the best of both types of hearing systems all in one device.

Page 5 goes on to describe the open fitting:

You will hear the difference – the whole world of sound

You will feel the difference – a new quality of life

Comfort and sound quality – the speaker is held in the ear by a soft dome...

Open for better perception – Since the ear is not plugged, your voice won't sound odd to you. The sounds of chewing and swallowing won't overwhelm your sense of hearing...

Enjoy the difference!

Pages 8 and 9 show an image of “Shape in use” (as being virtually invisible) and detail the “Advantages of Shape at a glance”:

Almost invisible – the transparent tube, together with the very small and inconspicuous housing, meets the highest aesthetic and discretion demands.

Superior sound quality – enjoy speech, music and the sounds of nature again.

A high level of wearing comfort – your ear is not plugged. Listening feels free and natural. The dome is soft and comfortable.

Minimization of feedback – with Shape’s unique configuration unpleasant whistling is a thing of the past.

You will hear the difference

Finally, page 10 shows the Shape configuration, which describes the interrelationship between the BTE, the tube and the external receiver unit.

Referring now to Exhibit 4, the front cover begins with a heading “**The best of both worlds...Shape**”. Page 2 shows an image of a BTE combining with a CIC to result in SHAPE. Page 3 describes the benefits of Shape:

A new dimension in hearing comfort – Shape

The best of both worlds – Shape has an external receiver which is located directly in the auditory canal. Shape therefore combines the advantages of smaller CIC hearing aid solutions with the high level of wearing comfort of open mini BTEs to form an efficient and comfortable product innovation.

Almost invisible – Shape is an extremely small and light weight hearing aid system. Due to its broad fitting range, Shape achieves the highest degree of speech understanding and hearing comfort for a greater part of your customer base.

One solution, two units – Shape’s receiver is placed in the auditory canal, providing the sound quality of a CIC. However, the digital signal processor and directional microphone system are positioned behind the ear – eliminating feedback and allowing for unprecedented level of discretion. There is no need to compromise one for the other – Shape offers the best of both worlds.

INTERTON is the first German company to offer you, in the form of Shape, a combination of excellent acoustic quality, open care, discretion, wearing comfort and durability.

Your customers will appreciate it.

Page 4 opens with “**The benefits to you – advantages for as far as the eye can see**” and “**Shape provides you with an efficient solution – all the advantages of an open BTE and a CIC are combined without compromise.**” Page 4 goes on to highlight the advantages of the BTE (*open fitting, high degree of comfort, cosmetically attractive, etc.*) as well as some disadvantages (such as *loss of acoustic quality through thin tube*). Page 4 also lists advantages of the CIC (*excellent acoustic quality, invisible*) as well as disadvantages (*Occlusion, less amplification, limited power, Expenditure in terms of time due to manufacturing of the shell, etc.*).

Page 5 lists the advantages of Shape, with no disadvantages. With regard to the **external receiver unit**, these include:

- *A broad fitting range*
- *Extremely high performance in the high frequencies (important for understanding speech)*
- *Optimum utilization of the residual volume of the auditory canal*
- *No thin tube – a cable instead (no loss in the high frequencies and no stationary wave resonances)*
- *No mechanical feedback (the result: excellent acoustic quality and improved understanding of speech)*
- *Open fitting*
- *Silicone parachute sits comfortably in the ear*

With regard to the **cosmetic appearance and comfort**, benefits include:

- Cosmetically attractive
- Light as a feather and almost invisible
- High degree of comfort
- Easy to handle, care for and operate

Page 6 reiterates:

Your customers will feel the difference – ... Shape is almost invisible and the ideal solution for customers who attach importance to an aesthetic appearance. Due to the open solution, former ITE users perceive their own voice much more naturally and benefit from increased comfort and an overall markedly improved quality of life.

Referring now to the introduction to Interton's technical datasheet at Exhibit 5, the qualities of the claimed configurations are summarized in part by:

Combining the advantages of BTE and ITE instruments, Shape brings the best wearing and listening comfort of both worlds to the customer. By having the receiver placed in the ear canal, it delivers excellent sound quality, a broad fitting range, and more gain. Shape is an occlusion free and invisible hearing solution with an attractive wearing style... No ear mould or shell is needed...

Shape is the most attractive, occlusion free and robust solution with the best sound quality and largest fitting range possible for open fittings. Altogether you will find that Shape is the direct route to better hearing. You will hear the difference.

14. As is evident from the above, Interton (just as did Oticon, Hansaton and Siemens) not only copies the claimed configuration, but lauds the configuration as innovative. Interton overtly details the problems and disadvantages of prior BTE and CIC devices

and provides detail on how the RITE open fitting solution solves all of the prior problems and disadvantages.

I declare under penalty of perjury that the foregoing is true and correct.


Leon Hirsch

November 21, 2006

EXHIBIT 1



Hearing Device Oticon Delta Named 'Best of Innovations' at Prestigious CES Innovations 2007 Awards

NEW YORK, Nov. 8 /PRNewswire/ -- At the International CES press preview today, the American Consumer Electronics Association (CEA), producer of the world's largest consumer electronics show (CES), announced that Oticon, A/S has been selected as an International CES Best of Innovations 2007 Design and Engineering Award winner. The "Oscars" of the electronics world honored the company's revolutionary Oticon Delta hearing device with the Best of Innovations 2007 in the Personal Electronics Products category. One of the most widely renowned consumer technology awards programs worldwide, Innovations 2007 recognizes the best-designed and best-engineered products in consumer technology. Judges awarded Oticon Delta one of the highest scores in the Personal Electronics category based on its value to a user, aesthetics, contributions to quality of life, and innovative qualities.

"It isn't often that a hearing device competes with hundreds of cutting-edge consumer electronics products from leading international electronics companies and comes out on top," states Niels Jacobsen, President and CEO of Oticon and William Demant Holding. "We designed Delta to change the way people view hearing aids. This award proves that we've moved the concept of hearing aids into competition with some of the most desired electronic equipment in the world. It is an incredible affirmation of the success of our mission to motivate image-conscious people with hearing loss to consider Delta as a high-tech, attractive solution."

The groundbreaking design that characterizes Oticon Delta has set a new benchmark in hearing aid design, creating a whole new category of hearing solutions. Delta features a miniature triangular design with sleek lines, hot colors and a brushed metallic surface. Its revolutionary design is made possible by placing its receiver into the ear canal at the end of a thin, transparent sound wire. Combining the best of two worlds, Delta merges the cosmetic advantages of in-the-ear instruments with the technological possibilities of behind-the-ear devices. Invisible behind the ear, the innovative design houses state-of-the-art digital technology allowing unprecedented sound quality and boosting speech understanding even in the most difficult listening situations.

The Best of Innovations award is one of many accolades the trendy hearing device has earned since its introduction earlier this year. A distinguished panel of international jurors awarded Oticon Delta the Red Dot Award 2006, one of the most sought-after design awards worldwide, for its superior design quality and innovative design. In addition, Delta received the design award of the Federal Republic of Germany 2007.

This year's Best of Innovations 2007 awards are given to the most honored products in each of 31 product categories. Products entered in this prestigious program are judged by a preeminent panel of independent industrial designers, engineers and members of the trade press to honor outstanding design and engineering in state-of-the-art consumer electronics.

Oticon Delta will be highlighted and displayed numerous times during the 2007 International CES which runs January 8-11, 2007 in Las Vegas, Nevada. The Best of Innovations Showcase will be on display at Innovations

Plus at the Sands/Venetian which houses the hottest emerging technologies in the consumer electronics industry. Delta will also be showcased in the Grand Lobby of the Las Vegas Convention Center and at CES Unveiled: The Official Press Event of the International CES from 4-7 p.m. on Saturday, January 6, in the Marco Polo Ballroom at the Venetian.

About Oticon

Oticon is one of the most innovative hearing aid manufacturers on the market. With over 100 years of experience, Oticon looks back on a number of technological breakthroughs in hearing aid history that have made a significant difference for people with hearing loss. Oticon is the only hearing instrument manufacturer with its own research center ensuring that the needs of hearing aid users are always put first when developing new solutions.

For more information about Oticon Delta please visit <http://www.my-delta.com>
<http://www.oticon.com>.

Contact: Sara Coulter
Pollock Communications
Phone: (212) 343-2149
scoulter@pollock-pr.com

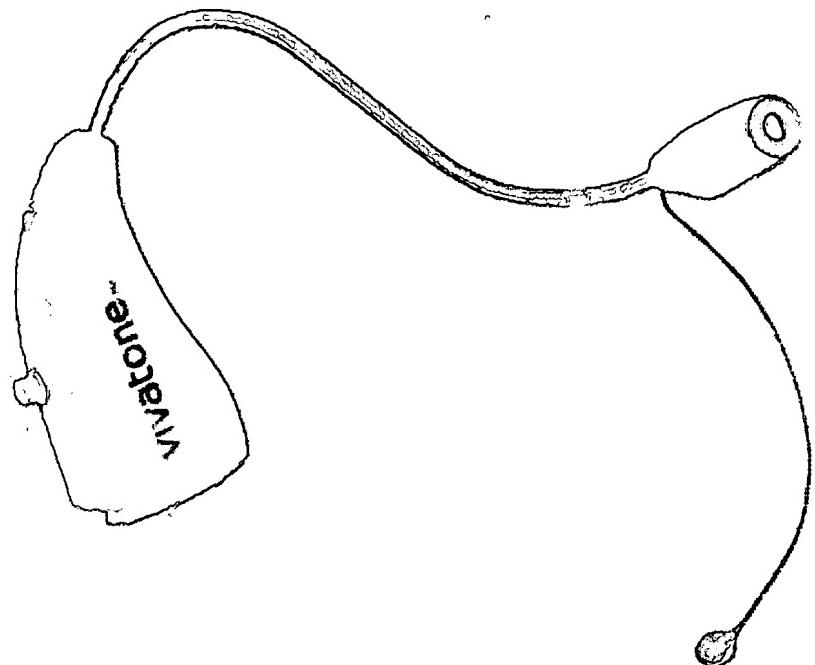
SOURCE Oticon

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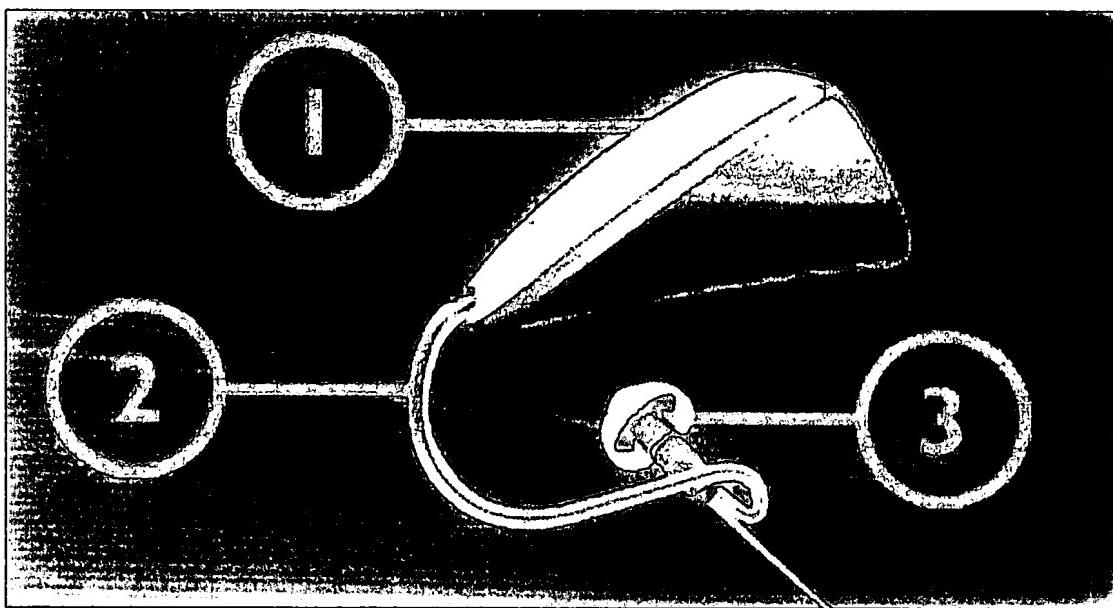
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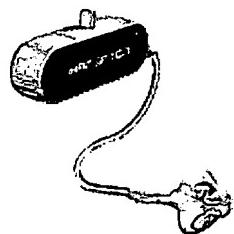
EXHIBIT 2



VIVATONE

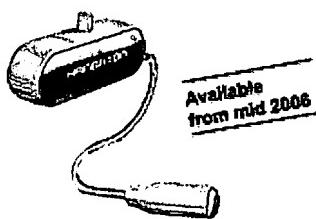


OTICON DELTA



**FREE SOUNDMANAGER
OPEN Variant**

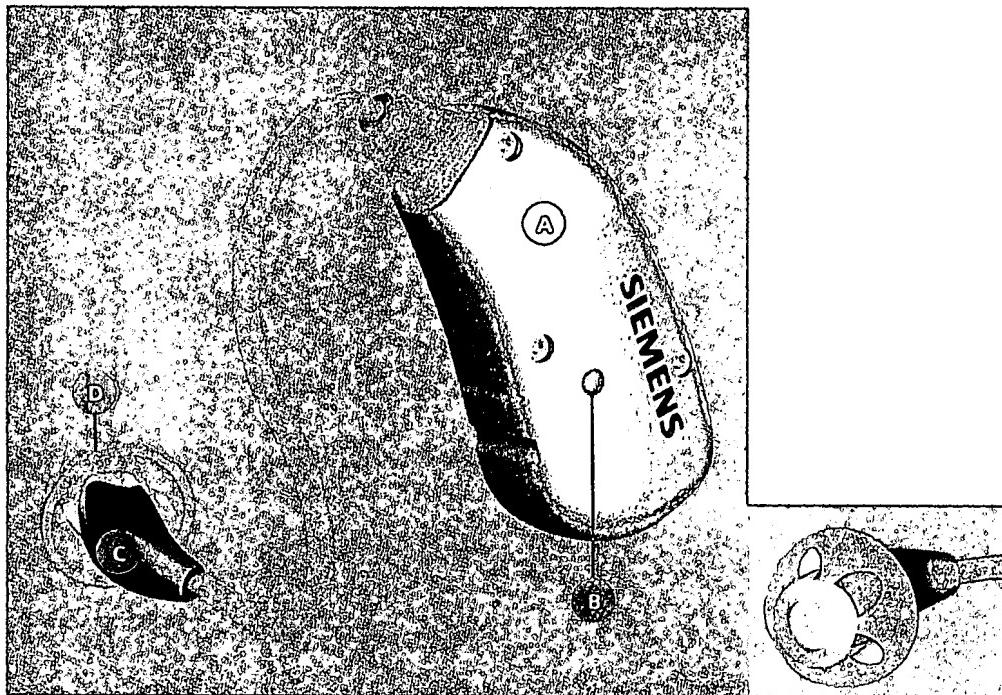
This system gets by without conventional earmoulds. Just put on and enjoy. You will love the FREE SOUNDMANAGER.



**FREE SOUNDMANAGER
NATURAL Variant**

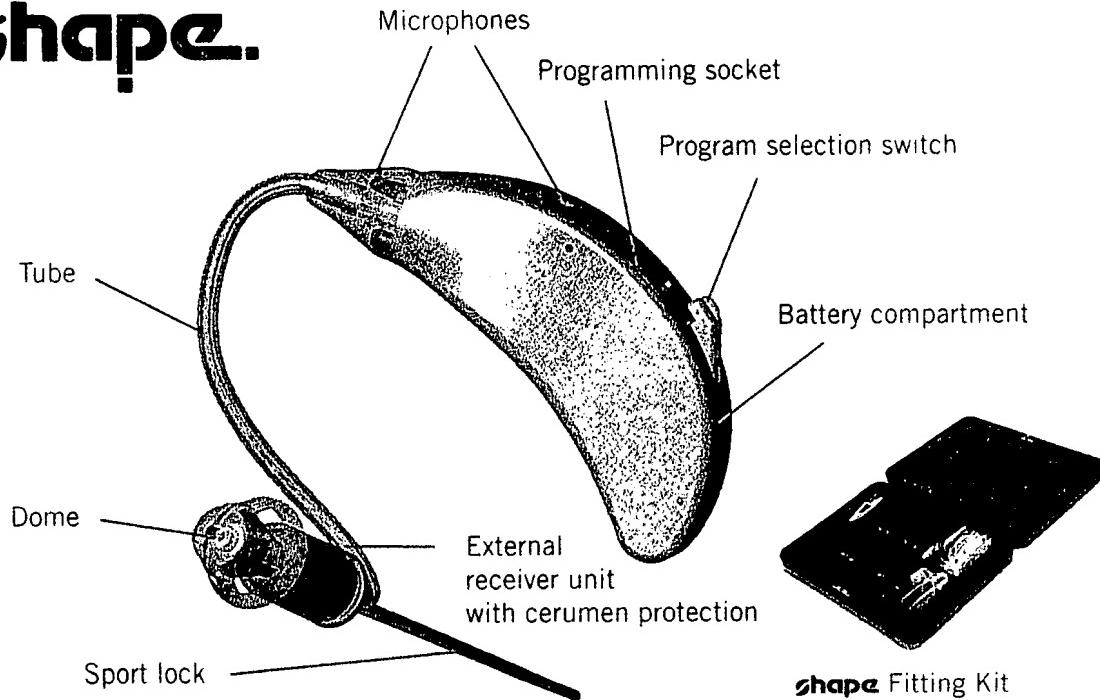
Experience the future superlative sound with the innovative natural technology. The receiver placed directly in the auditory canal with its almost invisible link enables excellent hearing enjoyment.

HANSATON FREE



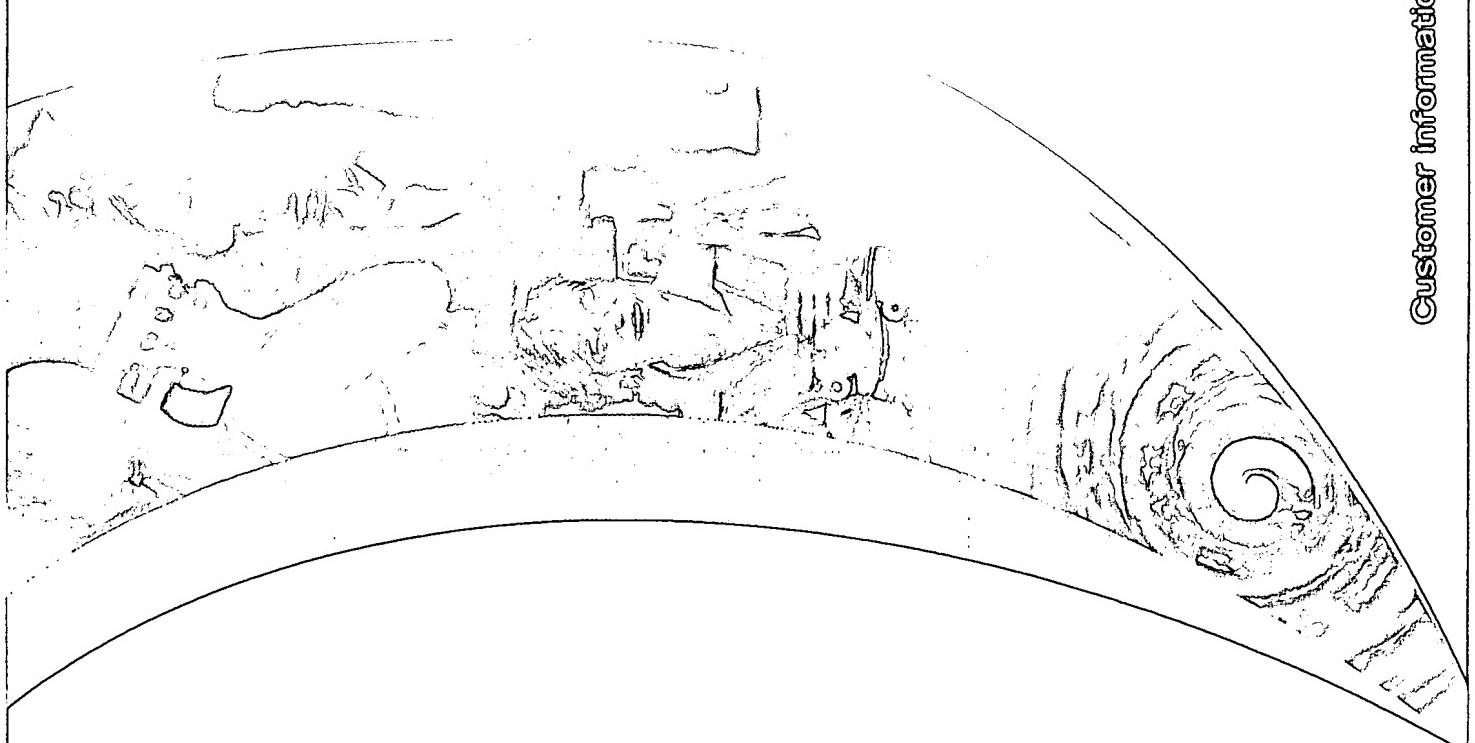
SIEMENS CENTRA ACTIVE

shape.

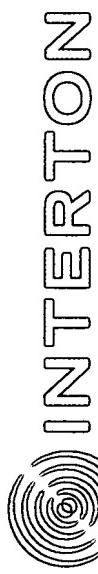


INTERTON SHAPE

EXHIBIT 3



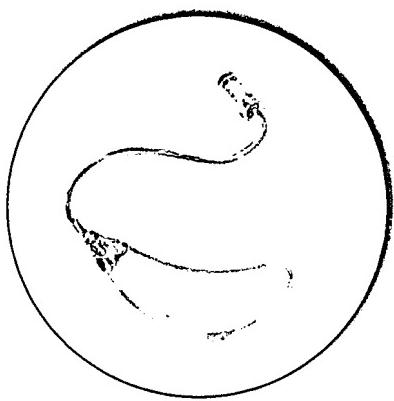
Customer Information



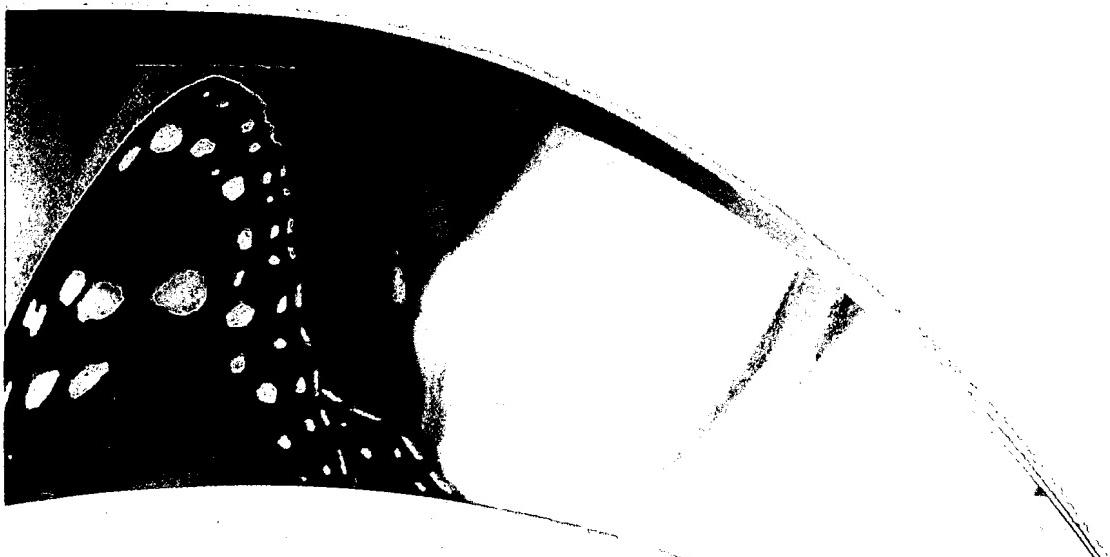
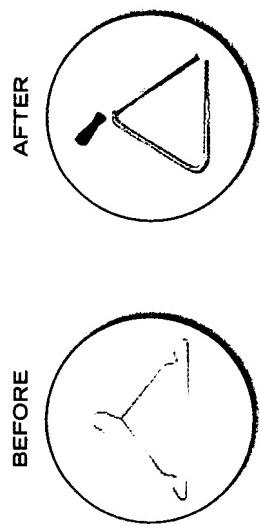
You will hear the difference

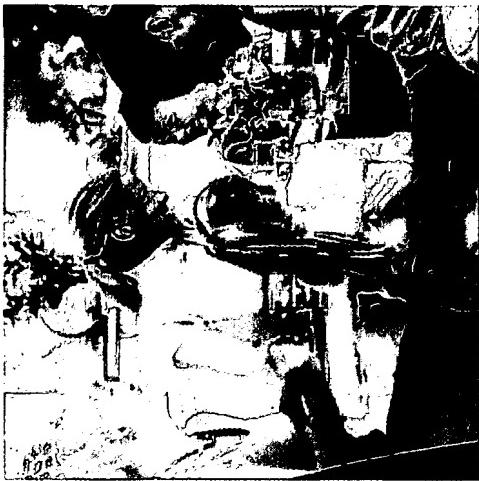
shape.

shape.



You will hear the difference





A new dimension in hearing comfort **shape.**

You have high expectations to your new hearing aid solution – you want an effortless hearing experience as well as the ability to understand conversations regardless of where you are. It is important to hear things that are going on around you, not just in front of you. You value a discreet, dependable and easy-to-use hearing aid system.

With **shape**, the world of sounds will open up to you again – imagine crossing a busy street on a sunny day and crowds of people are bustling to complete errands or attend meetings. **shape** processes sounds from all sides so you hear the bus pulling up behind you. You run into a good friend and when you catch up with each other, you can understand all of the conversation because by reducing the sounds of traffic and general background noise, your voice is emphasized.

Regardless of whether you are at a family gathering, a football match or in the middle of a quiet meadow on a spring day – with **shape** you will hear the rich world of sounds. You will hear the difference – effortlessly.

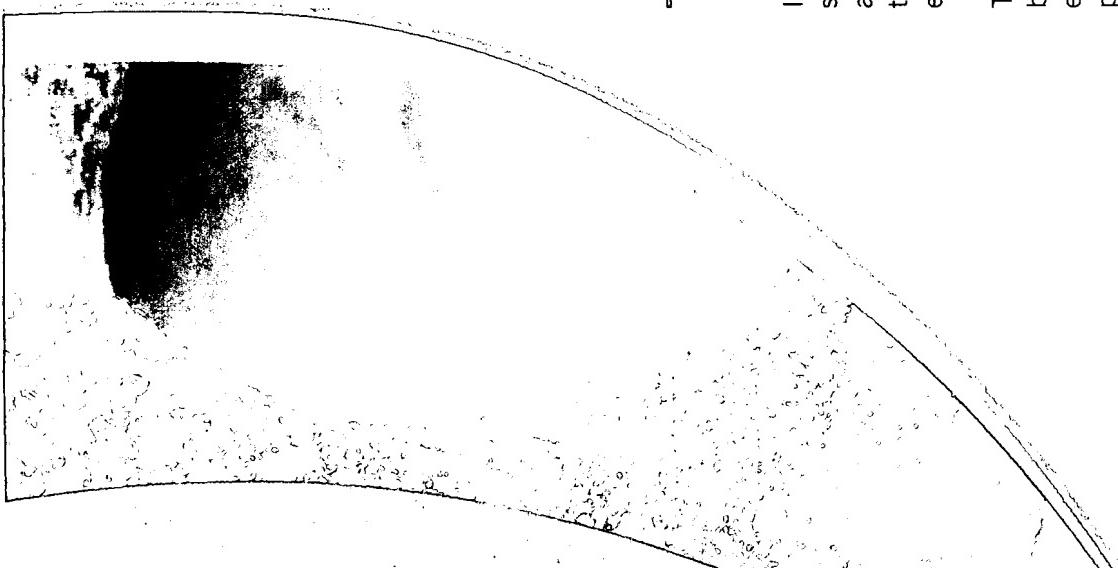
The secret of **shape**. – One solution, two units

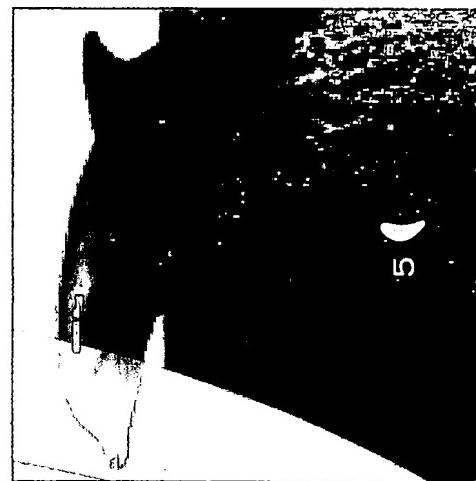
INTERTON strives to develop products that provide the best solutions for your needs. Our goal is to develop hearing systems that allow people to enjoy the world of sounds. Our products are developed to produce excellent sound quality and to feel comfortable while worn. The result of our most recent development is **shape**. With **shape**, INTERTON is the first German company to place the receiver (speaker) in the ear canal while the sound processor is worn behind the ear. The result: a highly effective hearing system that provides a much richer sound experience.

The speaker is positioned in the ear canal. The speaker is positioned in the ear canal, while the sound processor sits behind the ear. The units are connected by an invisible tube. By placing the speaker in the ear canal, it is closer to the ear drum than traditional hearing aids. This unique configuration makes excellent sound quality and cosmetic discretion possible.

shape – get all the advantages of in-the-ear solution (ITE's) and behind-the-ear solution (BTE's). Because all advantages are combined, **shape** offers many benefits. If you are an experienced hearing aid wearer, you are familiar with the advantages and disadvantages of different hearing systems.

With **shape**, there are no compromises – the best of both types of hearing systems all in one device.





You will hear the difference – the whole world of sound You will feel the difference – a new quality of life

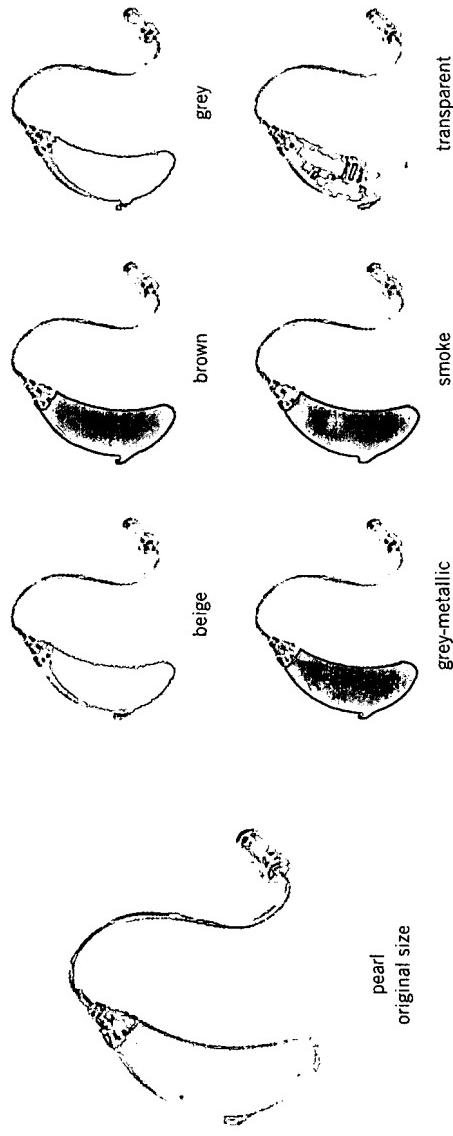
Comfort and sound quality – the speaker is held in the ear by a soft dome. This dome gives a very high level of wearing comfort because it prevents the "plugged up" feeling often associated with wearing hearing aids. This creates a more natural sound quality: sounds that you are able to hear unassisted continue to reach your ear naturally. **shape** assists your hearing only with those sounds that you otherwise would not hear.

For all purposes – **shape** is effective in any hearing situation. Whether watching television, talking on the telephone with a good friend or enjoying a dinner party. **shape** helps you experience more of the important things in life. Not only will conversations be easier to understand, you will also be able to enjoy the subtleties of the delicate sounds of life such as: the chirping of the birds, the babbling of a brook or the ringing of a doorbell. With **shape** you can hear everything again – effortlessly.

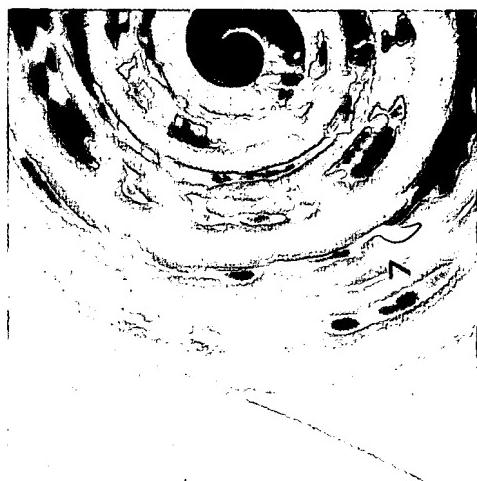
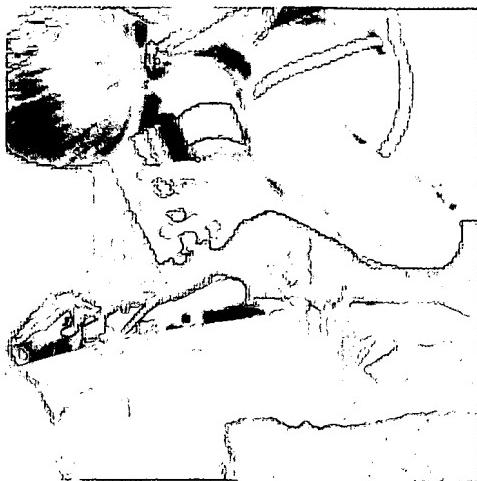
Open for better perception – Since the ear is not plugged, your voice won't sound odd to you. The sounds of chewing and swallowing won't overwhelm your sense of hearing. **shape** is 31 mm x 7.7 mm in size and weighs 2.2 g (including battery), making for a discreet and attractive solution.

Enjoy the difference!

shape - discover variety



D 6

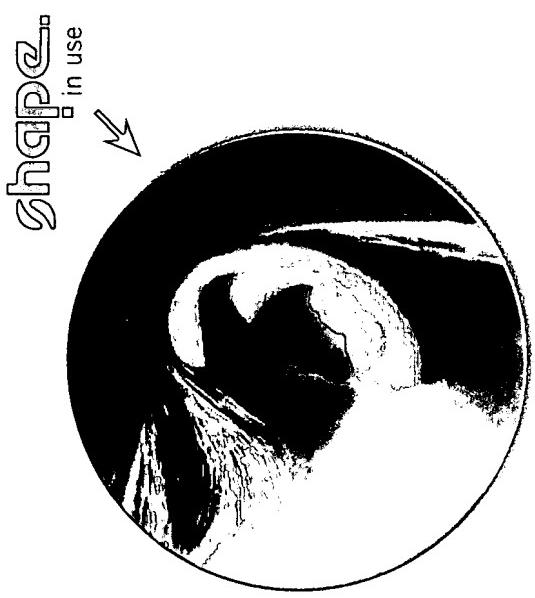


shape. makes life easier – pure hearing enjoyment!

shape is simply comfortable – the device can be adjusted to your personal wishes and needs. When you first wear your hearing aid, you will go through a phase of getting used to it – you will hear sounds that you have not heard for a long time. Your acoustician will support you with an optimal personalized adjustment for you. Now you will experience the full hearing enjoyment that **shape** provides you.

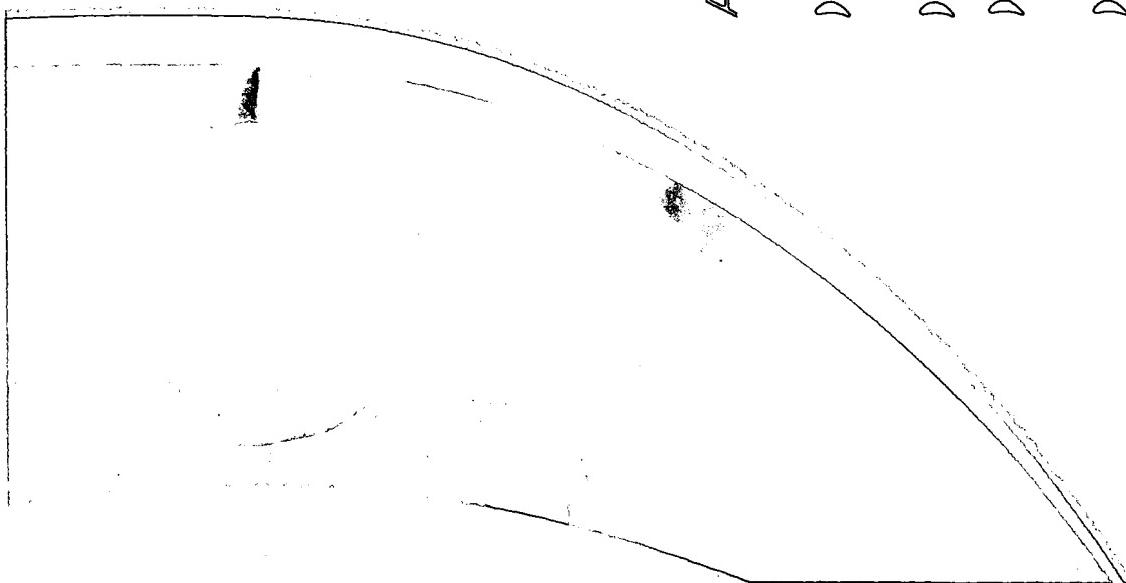
Once you use **shape**, you will never want to be without it and you do not have to. **shape** is made for daily wear. The soft and smooth dome has an additional protection to prevent earwax (cerumen) from penetrating the receiver. For the best performance the dome and cerumen protection should be replaced from time to time based on your individual needs.

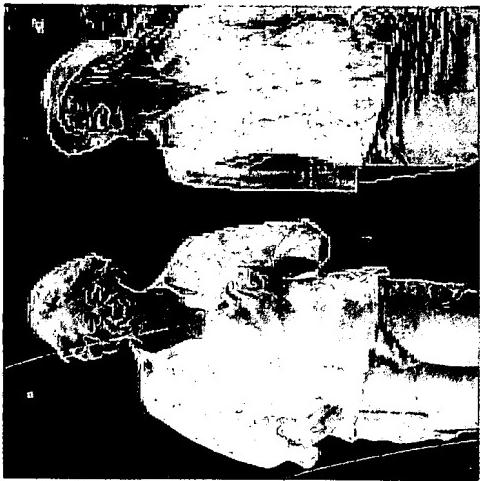
shape offers a unique combination of a dynamic world of sound, a high level of comfort, and a long lasting solution.



Advantages of **shape**. at a glance

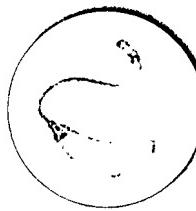
- ▷ Almost invisible – the transparent tube, together with the very small and inconspicuous housing, meets the highest aesthetic and discretion demands.
- ▷ Superior sound quality – enjoy speech, music and the sounds of nature again.
- ▷ Optimum understanding of speech in every situation – focus on the sounds that are important even when the environment is noisy.
- ▷ A high level of wearing comfort – your ear is not plugged. Listening feels free and natural. The dome is soft and comfortable.
- ▷ Minimization of feedback – with **shape**'s unique configuration unpleasant whistling is a thing of the past.
- ▷ Flexible service – your acoustic technician can adjust **shape** to meet your individual needs.





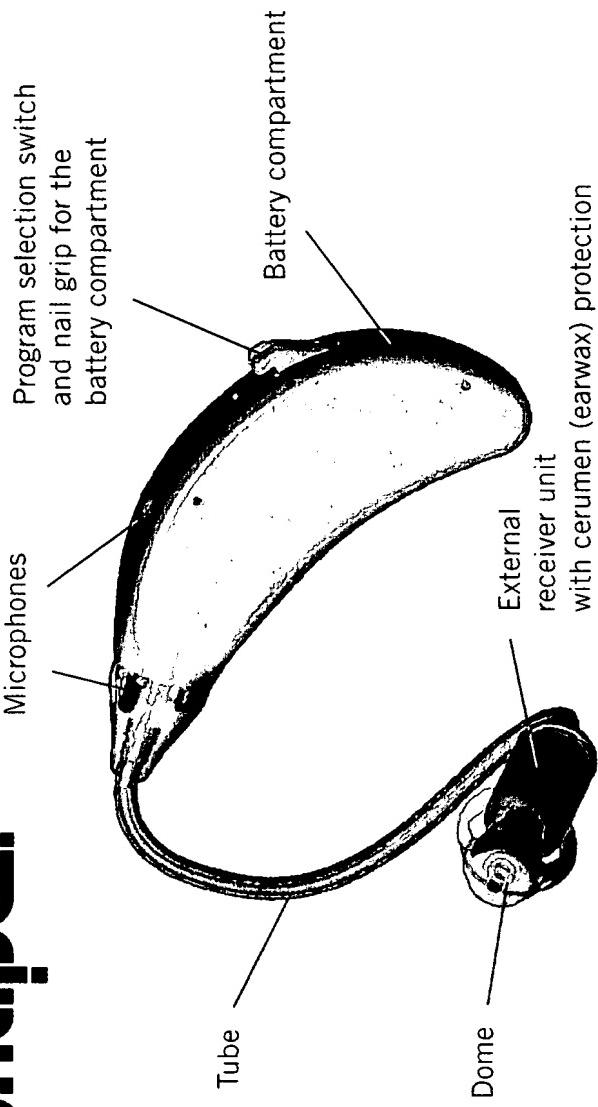
- High quality – You expect high quality products from INTERTON. The housing, plug connections, tube and receiver are manufactured from materials of the highest quality and are resistant to dirt and discoloration.
- Easy to operate and comfortable – multiple hearing programs can be controlled with a simple click. Switching on and off is simple and fast, just as the battery replacement. The rest of **shape**'s features operate automatically. Soft audible tones assist you by indicating which program has been selected, and a battery warning signal tells you when the battery life is running low.
- The result – a speech manager which is cosmetically attractive, light as a feather and technically sophisticated

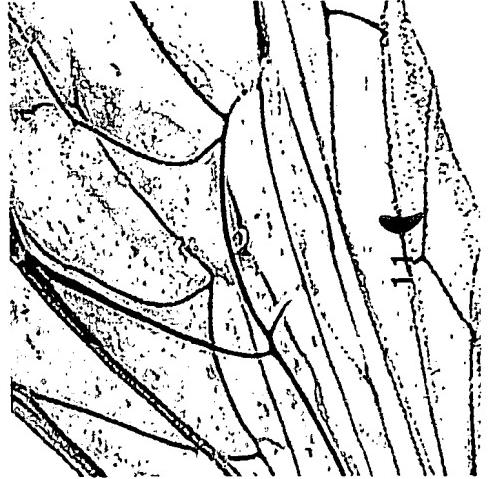
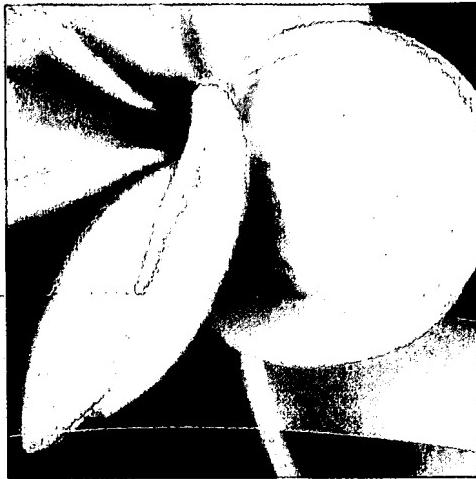
shape.



You will hear the difference

shape.

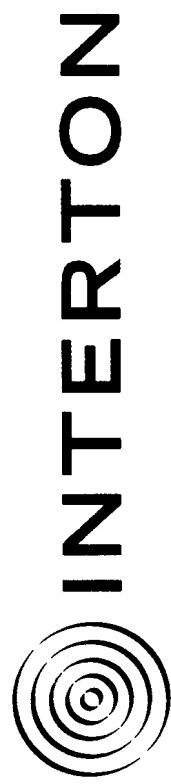


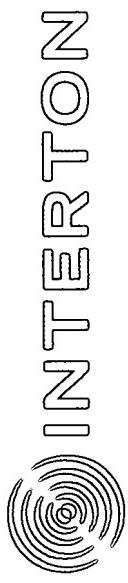


...continues to be a part of the right tone

For more than 40 years! A tradition that INTERTON is delighted about, and which gives the impetus to develop even more high performance products. Whether speech comprehension or hearing comfort, hearing at a distance or suitability for concerts is involved – it is only when the top technologists, who work in close collaboration with universities, see that the high demands of INTERTON's customers are fulfilled that INTERTON hearing systems can leave our premises.

Committed to technological and quality claims such as these, will it hardly come as a surprise to you that INTERTON is among the innovators in our sector. As one of the first, INTERTON has made pioneering developments such as "artificial intelligence" useful for hearing systems and has made them ripe for the market. INTERTON now belongs to the GN Great Nordic group – one of the leading international manufacturers of headsets and hearing aids – and is partner for "better hearing" for hearing aid acousticians and users in more than 50 countries.





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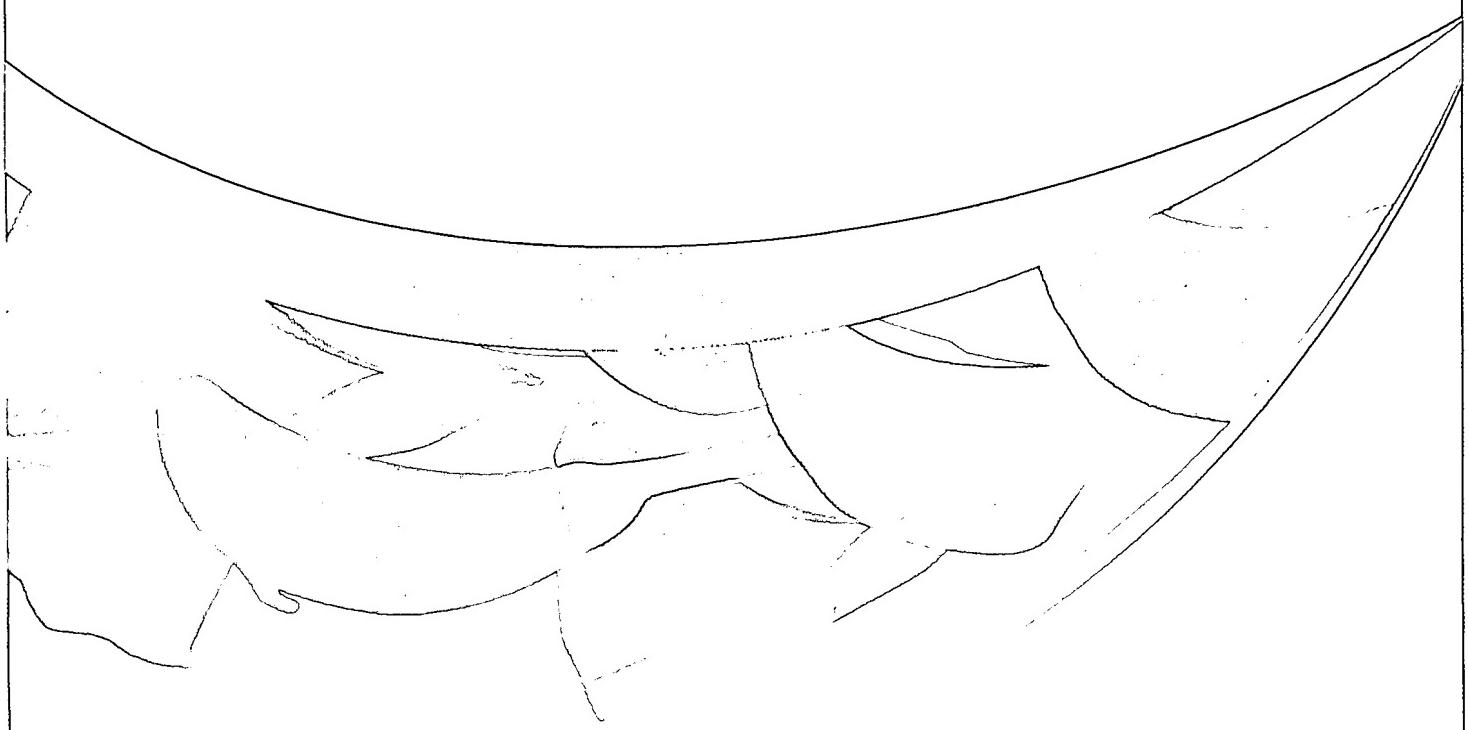
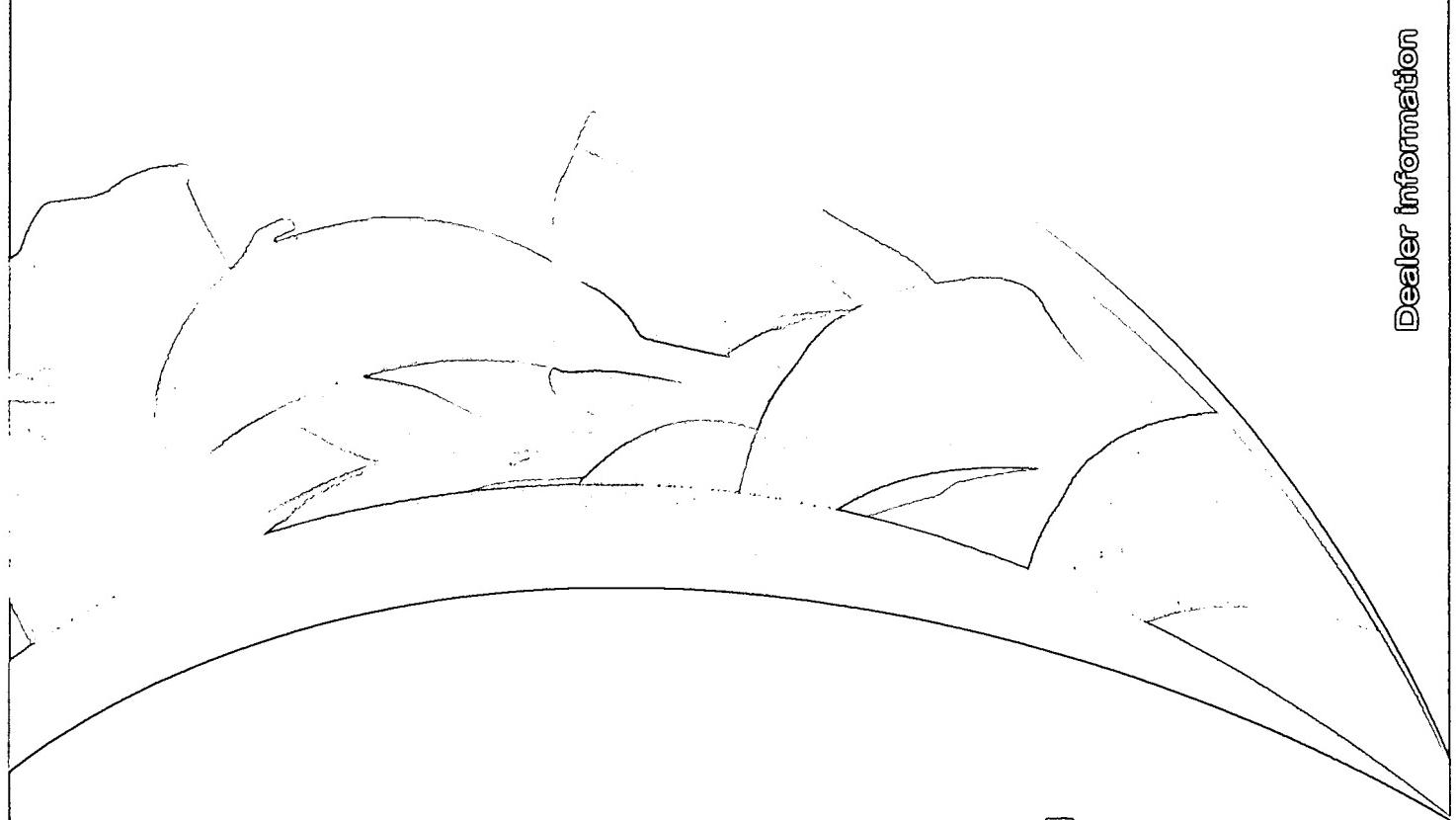
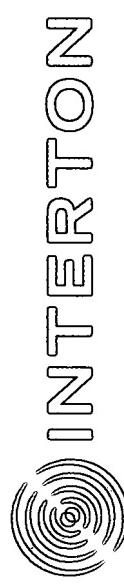


EXHIBIT 4



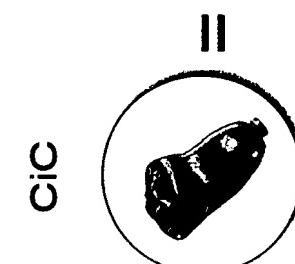
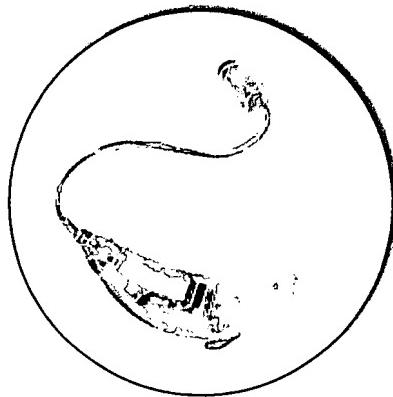
Dealer Information



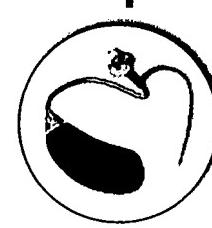
The best of both worlds

shape □

shape.

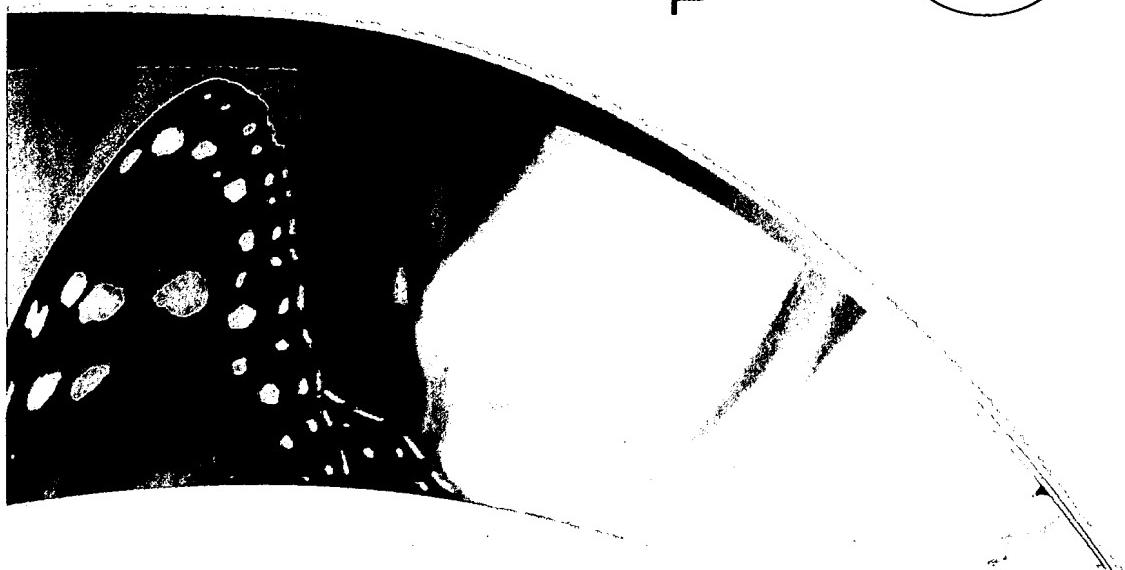


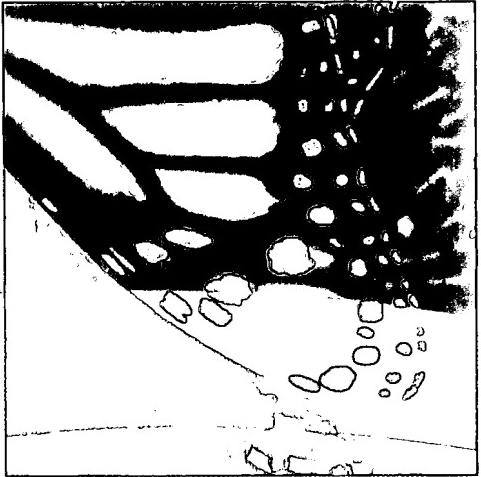
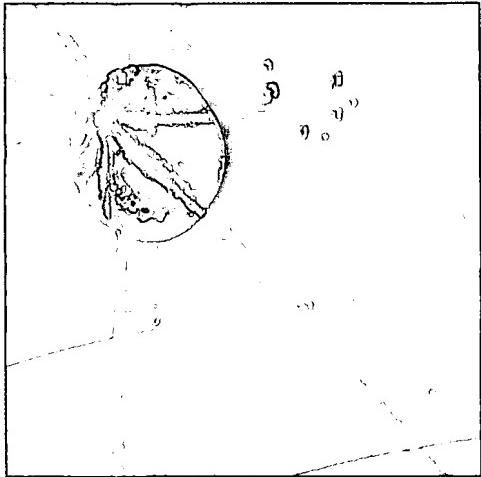
Cic



BtE
mini open

The best of both worlds





A new dimension in hearing comfort – **shape**.

The best of both worlds – **shape**, has an external receiver which is located directly in the auditory canal. **shape** therefore combines the advantages of smaller CiC hearing aid solutions with the high level of wearing comfort of open mini BtEs to form an efficient and comfortable product innovation.

Almost invisible – **shape** is an extremely small and light weight hearing aid system. Due to its broad fitting range, **shape** achieves the highest degree of speech understanding and hearing comfort for a greater part of your customer base.

One solution, two units – **shape**'s receiver is placed in the auditory canal, providing the sound quality of a CiC. However, the digital signal processor and directional microphone system are positioned behind the ear – eliminating feedback and allowing for an unprecedented level of discretion. There is no need to compromise one for the other – **shape** offers the best of both worlds.

INTERTON is the first German company to offer you, in the form of **shape**, a combination of excellent acoustic quality, open care, discretion, wearing comfort and durability.

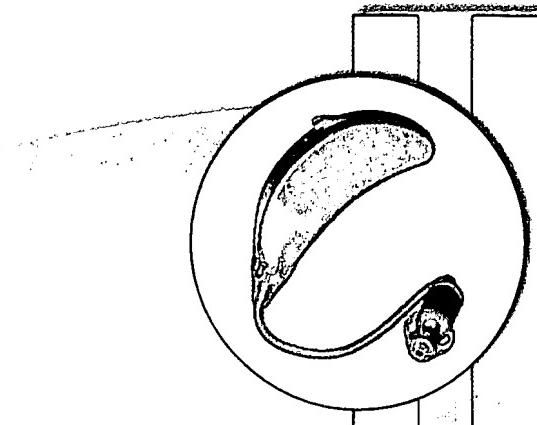
Your customers will appreciate it.

The benefits to you – advantages for as far as the eye can see

shape2 provides you with an efficient solution – all the advantages of an open BtE and a CiC are combined without compromise.

Mini open BtE	CiC	Advantages:	Disadvantages:
		<ul style="list-style-type: none">• Open fitting• High degree of comfort• Easy handling• Less repairs than with CiC• Immediate fitting• Cosmetically attractive• More control elements• Small, light-weight housing• Directional Microphone System <ul style="list-style-type: none">• Excellent acoustic quality• Invisible• Broad frequency range	<ul style="list-style-type: none">• Limited fitting range• Loss of acoustic quality through thin tube <ul style="list-style-type: none">• Occlusion• Less amplification, limited power• Small battery size <ul style="list-style-type: none">• Expenditure in terms of time due to manufacturing of the shell• Expenditure in terms of cost/time due to repairs of receiver & microphone• Directional Microphone System is not possible <ul style="list-style-type: none">• No manual controls





shape.

Advantages

EXTERNAL RECEIVER UNIT

- Broadband receiver provides a very broad fitting range
- Extremely high performance in the high frequencies, which is also important for understanding speech
- Optimum utilization of the residual volume of the auditory canal: more severe hearing losses can be treated with less amplification; making more amplification possible
- No thin tube – a cable connection instead: no loss in the high frequencies and no stationary wave resonances
- No mechanical feedback
- The result: excellent acoustic quality and improved understanding of speech
- Open fitting
- Silicone parachute sits comfortably in the ear
- Immediate adjustment possible
- Robust construction

PLUG CONNECTION

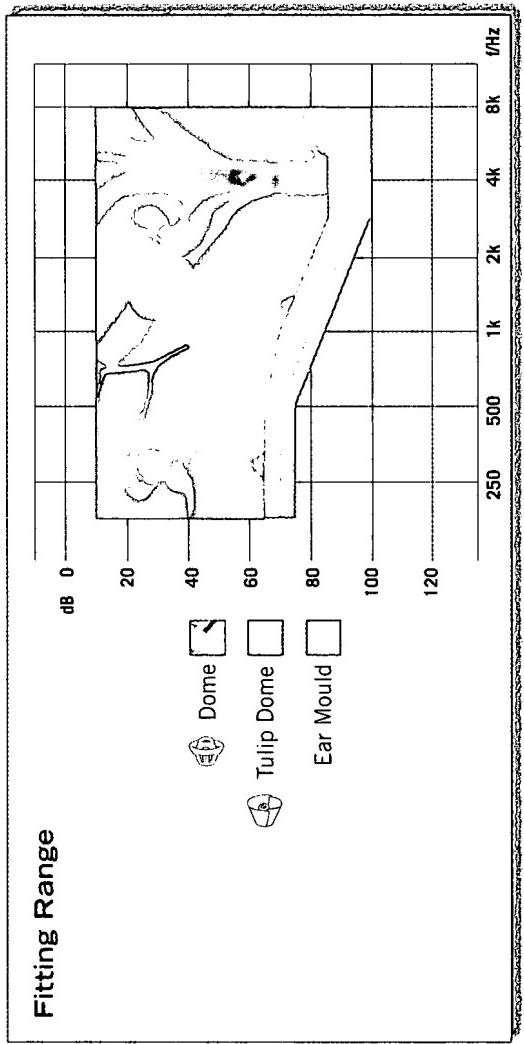
- Practical, robust coaxial connector
- Rotatable cable sleeve (45°) guarantees optimum adaptation to the shape of the ear and head offers added adaptability to customer's physical features
- Sturdy, sleek and seamless design
- Housing as a single casting: dirt and sweat resistant
- Size 312 battery provides more power, and longer use
- Program selection button for individual program selection
- Directional microphone system

COSMETIC APPEARANCE AND COMFORT

- Cosmetically attractive
- Light as a feather and almost invisible
- High degree of comfort
- Easy to handle, care for and operate
- Automatic adjustment to all hearing situations
- Automatic switchover to telephone mode
- Battery warning signal

SERVICE

- Instant fitting without waiting times
- Ear mould possible
- Quick, simple and cost-effective replacement of receiver unit



Your customers will hear the difference – the external receiver positioned within the auditory canal guarantees the acoustic quality of a CIC hearing aid solution. Therefore **shape**, has the amplification efficiency of a BTE solution.

Your customers will feel the difference – with a size of 31 mm x 7.7 mm and a weight of 2.2 g including the battery, **shape**, is almost invisible and the ideal solution for customers who attach importance to an aesthetic appearance. Due to the open solution, former ITC users perceive their own voice much more naturally and benefit from increased comfort and an overall markedly improved quality of life.

D 6

Reaching new customers – *shape*.

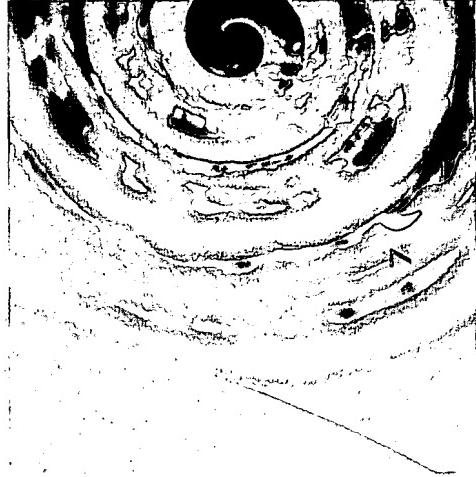
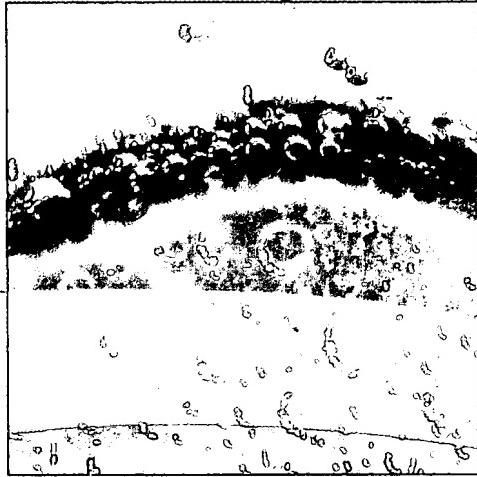
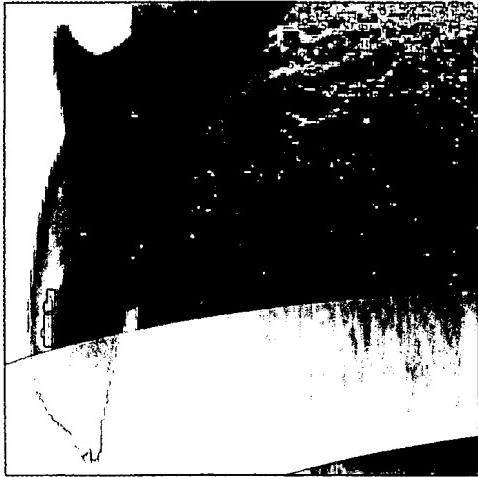
With *shape*, INTERTON has developed a hearing aid solution which attracts existing, new and undecided customer groups. Existing customers will want to try out this new device with outstanding signal processing and markedly better hearing results. During the initial purchase, new customers are attracted to *shape* for its aesthetics, comfort and for its state of the art technology. As for undecided customers who hesitate between a BtE and an ItE solution, you can offer them the "best of both worlds" with *shape*.

Open to everything: due to the wide adaptation range, even severe cases of hearing loss can be cared for on a more open basis. The possibility of incorporating the external receiver in an ear mould opens up the possibility of accommodating more existing BtE customers; who can now enjoy the excellent acoustic quality of a vented external receiver housed in the ear.

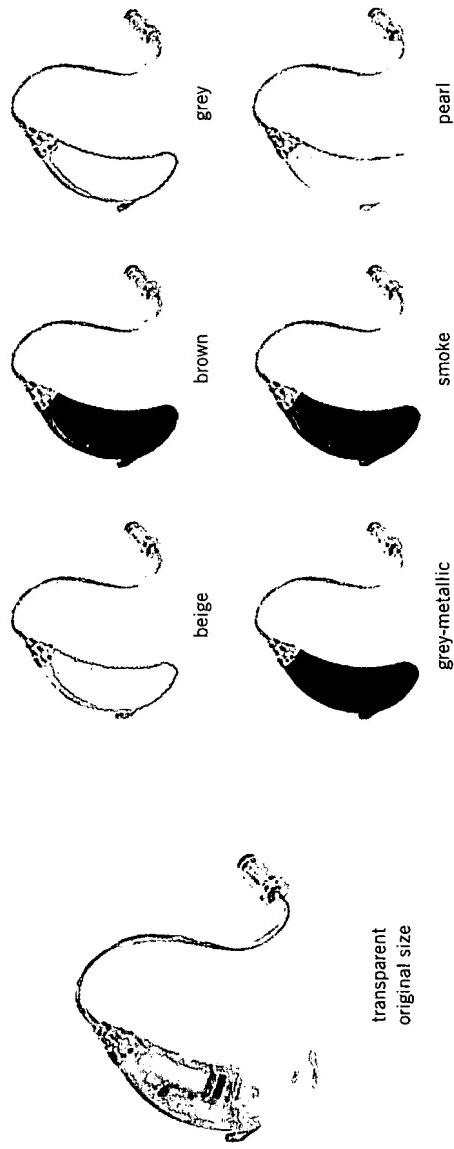
The *shape* Fitting Kit is ready at any time for instant use. In case of open fitting, direct adjustment on site is possible; there are no waiting times for the manufacture of an ear mould or shell – customer satisfaction is increased.

In addition to the technical details, great importance is attached to the stability and robustness of the system. A stable thing: the very high quality, gold-plated coaxial connector links the external receiver to the housing – the possibility of rotation to 45° allows individual adjustment to the shape of the head and ear. The dome and earwax protection prevent penetration of wax into the receiver. With regular replacement of both units, depending on the individual situation, the performance of the receiver is maintained. Since the ear is free of occlusion, earwax can run past the parachute naturally. Furthermore, the *shape* housing is cast in one piece and is therefore resistant to dirt and sweat.

Various test customers have worn *shape* a long period and have characterized it as a hearing aid solution with a high level of comfort and excellent speech understanding.



shape. makes hearing colourful



ADROTM
inside

Hearing high tech – ADROTM

The revolutionary signal processing, ADROTM (Adaptive Dynamic Range Optimization), has been incorporated into **shape**. ADROTM originates from cochlear implant research and optimizes the customer's existing dynamic range. Based on this, ADROTM allows an understanding of speech previously unknown, excellent cancellation of background noise and optimal three-dimensional hearing.

How does this work? Unlike conventional signal processing strategies, sound is not compressed, regardless of the volume. With traditional digital processors, loud and soft speech components are brought into restricted dynamics by compression, but with ADROTM, the speech is retained naturally in the residual dynamic range. With **shape**, this interval remains practically unmodified and therefore wide enough in order to understand speech with interference noise. The dynamics of sound are maintained in the existing residual dynamics – in a completely linear fashion, without ever becoming uncomfortably loud. The result: speech sounds more distinct and is easier to understand, which ensures a pleasant sound quality and optimum understanding of speech, even in noise.

ADROTM can be individually adapted to the customer's hearing loss like no other hearing aid, because ADROTM always ensures that the output signal remains comfortable. This is ultimately what counts for the customer. The signal processing functions individually in 32 channels – a division into so many frequency ranges is one strength of ADROTM and ensures the complete evolution of a pleasant acoustic pattern.

The personal hearing perception of your customer will be impressive: a comfort that your customers will come to appreciate. Together with the latest revised version of our fitting software CompuFit 4 – with a binaural fitting option and a guide leading through the fitting process – **shape** and ADROTM form an unbeatable team.

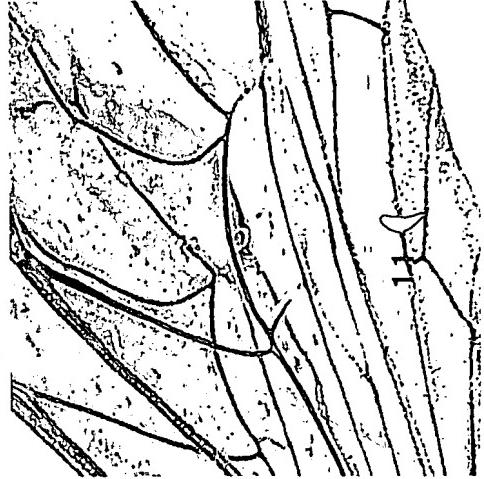
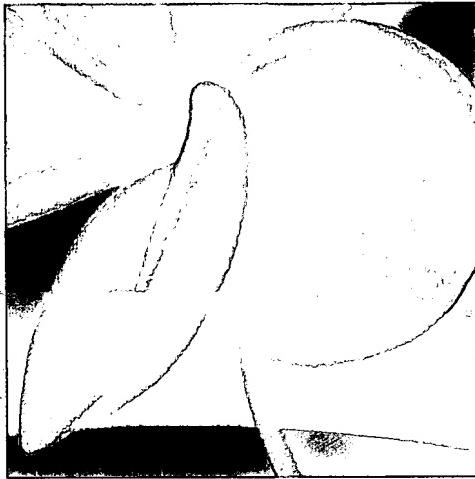


Do you value top performance?

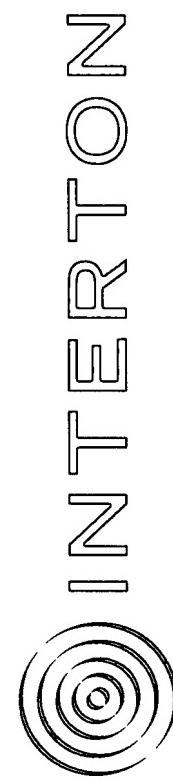
	Inside	ADRO Shape!	RITE*	Button	43*	113*	312	1,00	.32	3	✓	✓	✓	✓	✓	✓	MIP (Mobile Interference Protection)
Controls																	Low Battery Warning
Programs/Memories																	Inverse Feedback Manager
ABF (Adaptive Beamforming)																	At Ease (Suppressing Microphone Noise)
Channels/Bands																	Power Consumption (mA)
Battery Type																	dspl max. Output Sound Pressure Level
dspl Acoustic Gain (1600 Hz)																	Dual Microphone System
dspl max. Output Sound Pressure Level																	Batter Type
Power Consumption (mA)																	Programs/Memories
Channels/Bands																	At Ease (Suppressing Microphone Noise)
ABF (Adaptive Beamforming)																	Inverse Feedback Manager
Low Battery Warning																	MIP (Mobile Interference Protection)

* measured according to IEC 118-7

** RITE = receiver in the ear



INTERTON

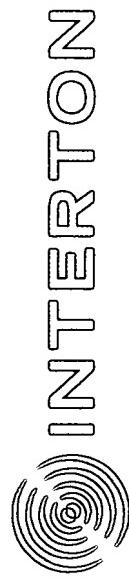


...continues to be part of the right tone

For more than 40 years! A tradition that INTERTON is delighted about and which gives the impetus to develop even more high performance products. Whether clarity of speech or hearing comfort, hearing at a distance or suitability for concerts is involved – it is only when the top technologists, who work in close collaboration with universities, see that the high demands of your customers are fulfilled that an INTERTON hearing aid system can leave our premises.

Committed to technological and quality claims such as these, will it hardly come as a surprise to you that INTERTON, through a 100% specialization in the development of the most modern hearing aid systems, are among the innovators in our sector. As one of the first, INTERTON has made pioneering developments such as "artificial intelligence" useful for hearing aid systems and has made them available for the market. INTERTON's innovators always have their ears and eyes directed towards what is happening in the world market.

Today, INTERTON has partners for "better hearing" in more than 50 countries and are affiliated with the GN Great Nordic group – one of the leading international manufacturers of headsets and hearing aids. INTERTON is still a family company and also consider you as a part of this family. For you and your customer's problems, INTERTON will always have an open ear.



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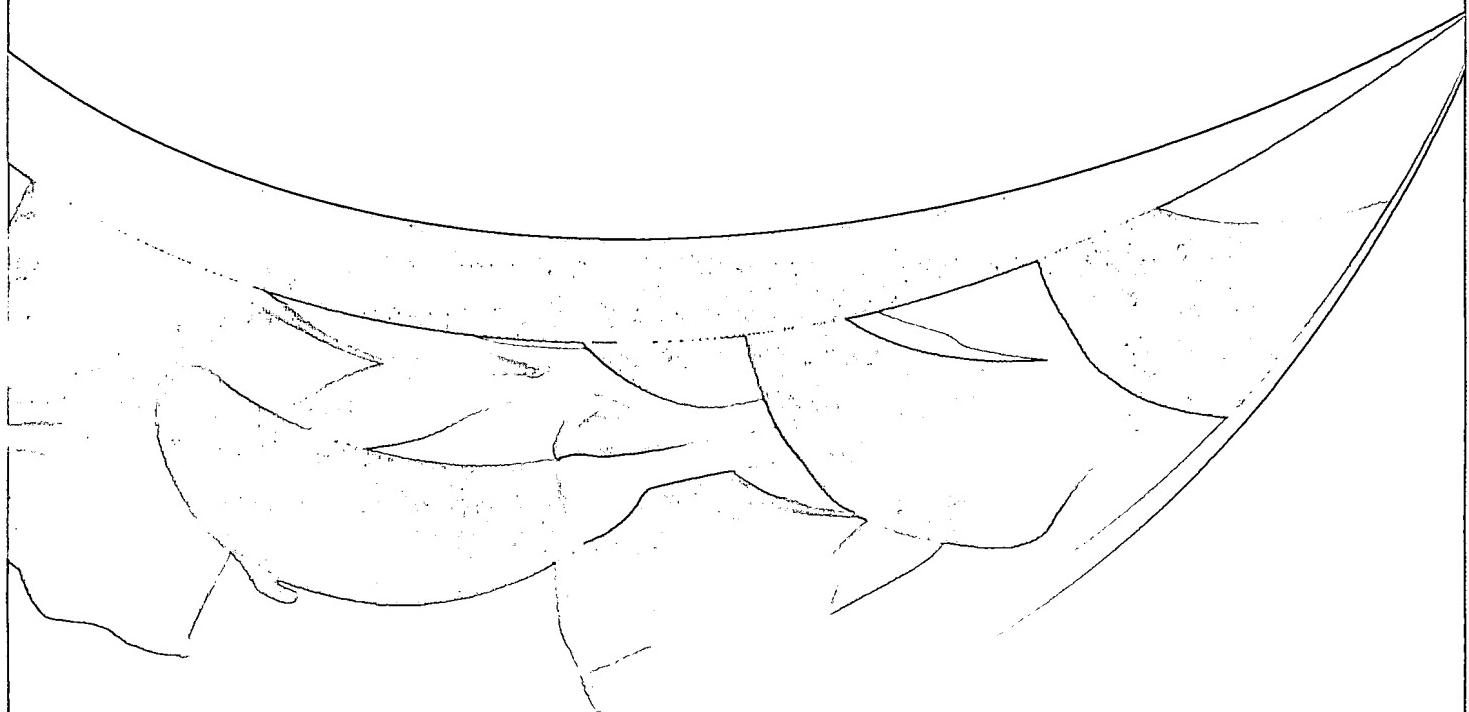


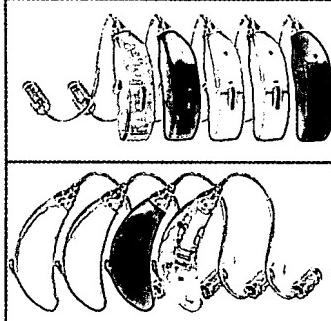
EXHIBIT 5

RITE

Shape



Technical Datasheet



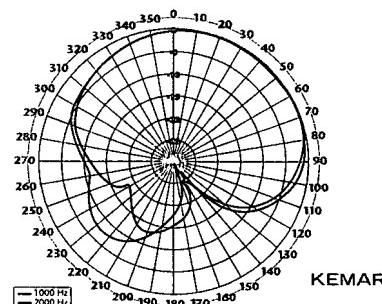
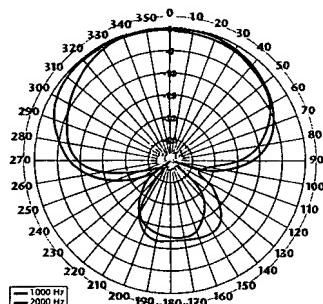
Combining the advantages of BTE and ITE instruments, Shape brings the best wearing and listening comfort of both worlds to the customer. By having the receiver placed in the ear canal, it delivers excellent sound quality, a broad fitting range, and more gain. Shape is an occlusion free and invisible hearing solution with an attractive wearing style. It can be fitted instantly; just choose the right tube and dome size. No ear mould or shell is needed. Nevertheless, the receiver can be combined with an ear mould to provide a more individual solution to the wearer if desired.

Shape is the most attractive, occlusion free, and robust solution with the best sound quality and largest fitting range possible for open fittings. Altogether, you will find that Shape is the direct route to better hearing. You will hear the difference.

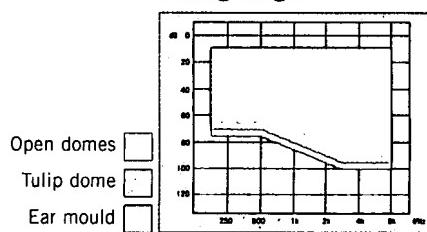
ADRO™ Trademark of Dynamic Hearing Pty Ltd.

AFM	The Adaptive Feedback Manager (AFM) automatically detects and removes unstable oscillation before it becomes audible feedback using an inverse signal. Feedback control can be activated independently in one or more memories for maximum comfort and performance.
ABF	Adaptive Beamforming (ABF) - An advanced directionality feature that tracks the location of unwanted noise and automatically reduces it. ABF can be activated independently in one or more memories.
MIP	Mobil phone Interference Protection (MIP): Optimum protection against interference during wireless phone transmission (GSM and DECT).
Comfort Scaling	A simple test procedure using signals generated by the hearing aid to determine the most comfortable output levels across a range of frequencies. These perceptual results form the basis for initial ADRO™ settings.
ADRO™	A new method of signal processing based on statistical estimates of the listening environment compared to perceptual estimates of Comfort and Audibility. This algorithm is designed to keep hearing aid output levels within an ideal range without the use of compression.
Standard Features	<ul style="list-style-type: none"> Signal processing in 32 channels Audible low battery warning Audible program switching signal Up to three comfort programs Directional microphone system Automatic telecoil
Software	<ul style="list-style-type: none"> NOAH or Standalone CompuFit 4.0 and higher
Colours	beige, grey, brown, smoke (black-medium transparent), pearl, red-metallic, silver, grey-metallic

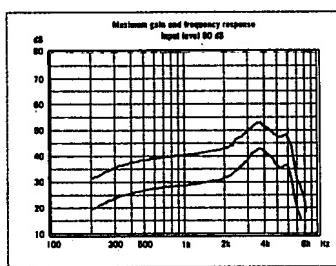
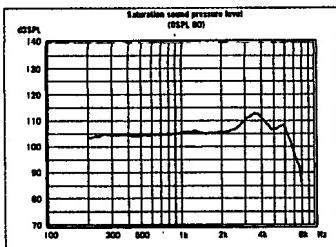
fixed directional (supercardioid)



Fitting range



INTERTON



The ADRO™ Rules - a simpler and more efficient hearing aid fitting

ADRO does not use compression to compensate for a reduced dynamic range. Instead, amplified output levels are monitored and adjusted in each of 32 channels whenever an ADRO rule is violated. With ADRO there is no need to adjust compression ratios, threshold knee-points or attack/release times!

Audibility rule

70% of all amplified sounds must fall at or above the Audibility boundary, a level defined as "soft but above threshold". If the distribution of amplified sounds shifts too low in level, the Audibility Rule will be violated and gain will be increased until the desired condition is restored. This process occurs in each of 32 channels.

Comfort rule

90% of all amplified sounds must fall at or below the Comfort boundary, a level defined as "the most comfortable level". If the distribution of amplified sounds shifts too high in level, the Comfort Rule will be violated and gain will be decreased until the desired condition is restored. This process also occurs in each channel.

The Audibility and Comfort boundaries define the desired output range in each channel. These boundaries are determined from in-situ measurements of loudness or calculated from the audiogram.

MOL rule

The output level can never exceed the Maximum Output Level. This rule prevents sudden impulsive sounds from causing loudness discomfort.

Electroacoustic performance Shape		IEC 118-7	IEC 118-0	ANSI S3.22
Acoustic gain				
at 1600 Hz (dB)	43	49	-	
at 2500 Hz (dB)	46	55	-	
Peak value (dB)	52	63	52	
Saturation sound pressure level SSPL				
at 1600 Hz (dB SPL)	105	114	-	
at 2500 Hz (dB SPL)	107	116	-	
Peak value (dB SPL)	113	124	113	
ANSI-HFA				
Acoustic gain (dB)	-	-	42	
Saturation sound pressure level (dB SPL)	-	-	106	
Low-frequency limit (Hz)	200	200	200	
High-frequency limit (Hz)	7500	8000	7700	
Sensitivity of induction coil				
at 1600/2500 Hz and 1 mA/m (dB)	63/71	73/80	-	
HFA SPLITS (dB)	-	-	73	
STS (dB)	-	-	1	
Harmonic Distortion (THD)				
at 500 Hz (%)	1	1	1	
at 800 Hz (%)	1	1	1	
at 1600 Hz (%)	1	2	1	
Equivalent input noise (dB)	18	20	18	
Power consumption (mA)	1,0	1,0	1,0	
Battery type	312	312	312	

Technical specifications

Signal processor	
DSP clock speed	5.12 MHz
Sampling rate	16 kHz
Analog-Digital Converter	Resolution 16 bit
DSP-Process	"Adaptive Dynamic Range Optimization" (ADRO™) in 32 channels
ADRO™ Audibility rule	Mid (70 %) percentile > Audibility boundary
ADRO™ Comfort rule	High (90 %) percentile < Comfort boundary
ADRO™ MOL rule	LA max < MOL
Maximum Output Level (MOL)	in 32 channels
Comfort Scaling	Adjustable in the audiologic frequencies
Feedback Cancellation	
Adaptive Feedback Manager (AFM)	Automatically detects and removes feedback
Adaptive Beamforming (ABF)	Tracks the location of unwanted noise and automatically reduces it. ABF can be activated independently in one or more memories.
Automated telecoil	Switches automatically to the telecoil program as soon as a telephone gets placed at the device.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

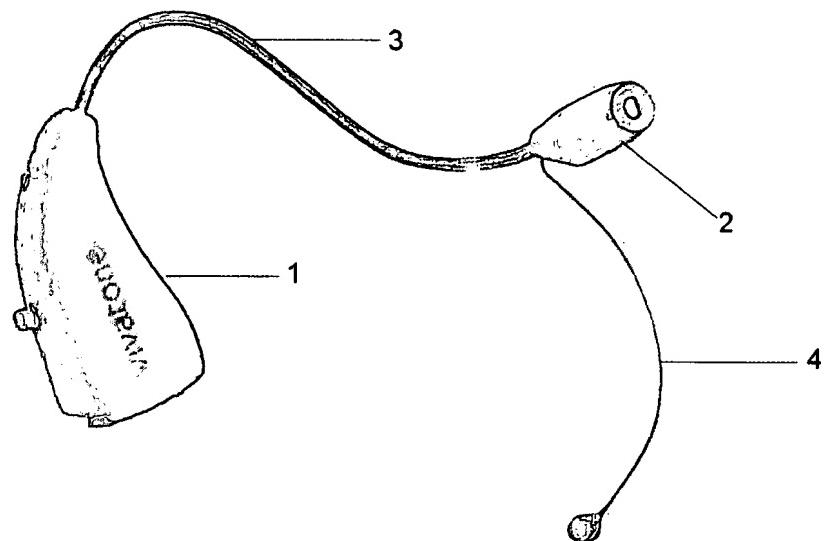
Leon Hirsch declares and says that:

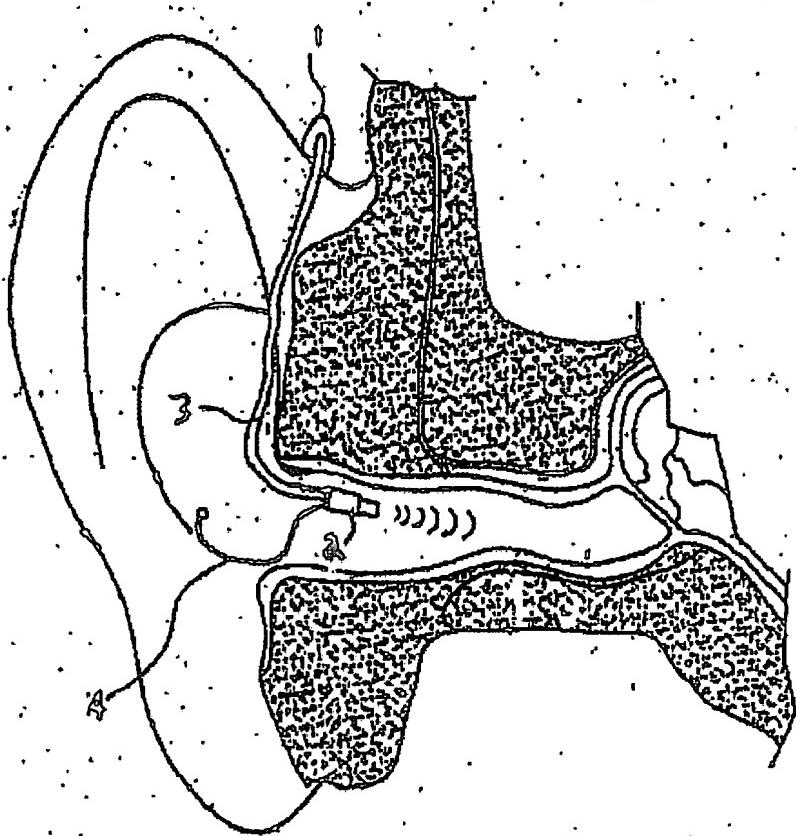
1. I am President of Vivotone Hearing Systems, LLC ("Vivotone"), and assignee of the above-referenced application. I have been intimately involved in the development, manufacture and sale of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal since 2002.
2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:
 - a hearing aid system, comprising:
 - a microphone sampling position located externally of an ear canal of a user,
 - a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through

the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration, wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. As noted in my Declaration of October 31, 2006, the claims of the above-referenced claims correlate with the commercial Vivotone open ear hearing aid system. Reference is made to the following images of the commercial Vivotone device as an aid to review of the following claim chart:





The following claim chart relates aspects of the claimed Vivotone hearing aid to commercialized Vivotone hearing aid to which the above-described commercial success figures above relate. Relevant portions of independent claims (which portions are substantially reproduced in the remaining independent claims) are reproduced below:

A hearing aid, comprising: a microphone sampling position located externally of an ear canal of a user;	The Vivotone hearing aid includes a microphone and microphone port located within the behind-the-ear component (1).
a receiver comprising a speaker positioned in an open ear configuration and suspended within the ear canal;	The receiver (2) comprises a speaker (5) provided within the ear canal in an open ear configuration and is suspended within the ear canal by virtue of the stiffness of the intermediate wire (3) and/or the effect of the concha wire (4).

wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an open ear configuration;	The sampled sounds are passed to an amplifier provided in the behind the ear component (1), amplified in accordance with hearing loss programming and are relayed to the speaker (5) via the intermediate wire (3), which is provided around a portion of the external ear into the ear canal opening.
wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit	The microphone port and amplifier are both contained within the behind the ear component (1).

The additional aspect of the independent claim 1 is also embodied in the commercial Vivotone device, including the receiver generating about three decibels or below of insertion loss over a portion of human ear audible frequencies.

4. My open ear hearing aid was first commercially launched by Vivotone in the first quarter of 2004, and is embodied in a product designated the “Vivotone Mini”, the “Vivotone Standard” or the “Vivotone Dual”. At the time of the open ear hearing aid commercial launch, Vivotone, as a small startup company whose product line consisted solely of the open ear hearing aid product, did not have any prior reputation or name recognition. Further, there were not any significant efforts or expenditures with regard to advertising the open ear hearing aid. Indeed, Vivotone did not engage in any television or radio advertising, and only minimal other national advertising. National advertising expenses were \$1,500 in 2004 and \$16,000 in 2005, which amount is extremely minimal. Notwithstanding the lack of name recognition and advertising, Vivotone’s open ear hearing aid has achieved a high degree of commercial success. Sales were generated principally by word of mouth by audiologists, and by side-by-side demonstrations of Vivotone’s open ear hearing aid system with other hearing aids. As may be seen from the sales charts at Exhibit 1 of my September 13, 2006 Declaration, domestic unit sales and

domestic net revenues have steadily increased from the first quarter of 2004 until December 31, 2005. Domestic net revenues were \$27,000 in the first quarter of 2004, \$3,420,000 for the full year of 2004, and more than quadruple that in 2005 to \$14,500,000, including international sales. In other words, in a short two-year period, the sales of Vivotone's open ear hearing aid went from no sales to almost eighteen million dollars. Those sales came despite minimal advertising and no name recognition or prior reputation in the hearing aid field.¹

5. Various types of hearing aids have been sold marketed and sold for more than 30 years, including completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately adjacent to the ear canal (e.g., in the bowl of the ear). BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing behind the ear and an open tube for directing sound to the ear canal from the speaker housed in the BTE. The Vivotone open ear hearing aid is the FIRST product in those 30 some odd years to incorporate a design that separates the amplification from the speaker, placing the amplification behind the ear (like a BTE device, but unlike the CIC, ITC and ITE devices) while at the same time suspending a small profile speaker in the ear canal to give an open ear configuration. Thus, it took the industry 30 some odd years to create Vivotone's novel open ear hearing aid system configuration, which system minimizes insertion loss and occlusion effect and uses the ear's natural "receiver" to the fullest, mixing natural sounds and amplified sounds in the ear for excellent sound clarity (see the Vivotone Hearing System's brochure at Exhibit 2 of my September 13, 2006 Declaration).

6. While various types of hearing aids have been known for decades, no other company in the hearing aid field was motivated to separate the microphone sampling and

¹ However, since the introduction of the Oticon and Hansaton hearing aid products, which as discussed hereafter, constitute copies of our claimed invention, U.S. domestic sales of the Vivotone product have declined.

amplification from a suspended in-canal speaker (to provide an open ear fitting remote from the BTE microphone and amplifier) until the Vivotone open ear hearing aid in 2004. In my opinion, this fact alone indicates that it was not obvious to provide for such a novel open ear configuration in a hearing aid system.

7. Our open ear hearing aid system resolves the biggest problems that hearing aid wearers experienced prior to the introduction of the Vivotone hearing aid solution: occlusion, insertion loss, feedback and resonance effects (depending on the type of hearing aid used). Occlusion is the “head in the barrel” effect created when the hearing aid wearer speaks or chews. Feedback is the whistling sound experienced when a patient places a telephone near the ear or other structure. Feedback is similar to the whistling sometimes heard in an auditorium when the microphone is too close to the speaker. Further, BTE devices feeding sound to the ear canal via a sound tube suffer from resonance effects. Vivotone revolutionized hearing aids by developing a product that eliminates the *long felt need* with regard to each of these annoyances. That is, Vivotone enhances hearing while enabling the wearer to enjoy normal speaking, eating or telephone conversation without interference.

8. The reason that Vivotone hearing aids are able to provide these benefits is its unique design. Vivotone’s microphone and amplifier are housed in a small plastic case located behind the ear. Unlike other hearing aids, Vivotone delivers sound from the microphone port in the BTE electronically to its speaker in the open ear canal. The speaker is small enough to allow the ear canal to remain open, and therefore, is non-occluding. This revolutionary approach has advanced the acceptance of hearing aids significantly. As noted, prior to Vivotone, hearing aids either occluded the ear canal or transmitted sound from a speaker located behind the ear to the ear canal through a plastic tube. These designs cause either occlusion or insertion loss or distortion or lack of clarity. Vivotone’s open ear speaker allows the patient’s residual natural sound to combine with the enhanced hearing provided by Vivotone’s processor, giving crisp, clear sound to the patient.

9. I noted in my Declaration of September 13, 2006 that Oticon introduced the “Delta” hearing aid product in February, 2006 and that Hansaton announced the “Free Soundmanager” hearing aid in March, 2006. Both of these companies are direct competitors of Vivotone. These companies copied our open ear hearing aid invention and aggressively marketed and highlighted the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

10. I also noted in my Declaration of October 31, 2006 that on October 17, 2006, Siemens announced its own RIC (“Receiver in the Canal”) hearing aid, called the “CENTRA Active”, which is to be released in the beginning of 2007. This company also copied our open ear hearing aid invention and is aggressively marketing and highlighting the benefits of our open ear hearing aid invention as being a significant advance in the hearing aid field.

11. I also noted in my Declaration of November 28, 2007 that Oticon was recently selected as an International CES Best of Innovations 2007 Design and Engineering Award winner for its Delta product (which, as previously discussed, is a copy of the Vivotone’s claimed invention) and that a fourth Vivotone competitor, Interton Horgerate, GmbH, recently announced a new RITE (Receiver in the Ear) product, called Shape.

12. It has recently come to my attention that even another large competitor, Phonak, has also announced a copying product, the microSavia Art CRT (“Canal Receiver Technology”). Exhibit 1 illustrates the new microSavia Art CRT receiver, including technical data and a user manual. This provided additional evidence that Vivotone’s configuration is being copied over and over again by our major competitors. Like the others, the microSavia Art CRT device (see page 5 at Exhibit 1) includes the BTE component (2) with hearing aid electronics, including the microphone inputs behind the ear (1), a receiver (3) in the ear in an open ear fitting, and a thin wire connecting the open ear receiver to the rest of the electronics in the BTE.

13. The Phonak manual describes the microSavia Art CRT hearing system ("Canal Receiver Technology") as follows:

This inconspicuous hearing system provides – in a fully automatic manner – the highest sound quality, speech understanding and listening comfort in all your personal hearing situations, and all this in a micro-sized instrument.

14. As is evident from the above, yet another large competitor, Phonak has copied the Vivotone configuration (just as did Interton, Oticon, Hansaton and Siemens).

I declare under penalty of perjury that the foregoing is true and correct.

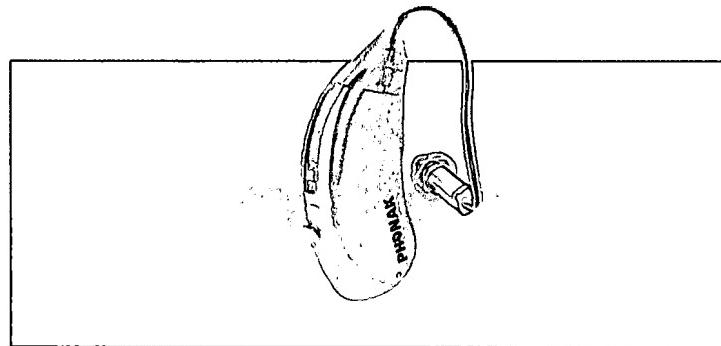

Leon Hirsch

March 13, 2007

EXHIBIT 1

microSavia Art™ CRT
Canal Receiver Technology

User Guide



PHONAK
hearing systems

CE
0459

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Welcome

Congratulations on choosing the microSavia Art CRT hearing system (CRT stands for Canal Receiver Technology), the smallest and most sophisticated external receiver instrument from Phonak. microSavia Art CRT uses the latest advances in digital hearing technology to offer you the ultimate combination of miniaturization, hearing performance and comfort.

This inconspicuous hearing system provides – in a fully automatic manner – the highest sound quality, speech understanding and listening comfort in all your personal hearing situations, and all this in a micro-sized instrument.

microSavia Art CRT is a quality product developed by the Swiss company Phonak, a world leader in hearing technology, innovation and reliability. Please read this manual carefully to benefit from all the features of your new hearing system. With proper care and usage, your microSavia Art CRT will support your hearing and understanding for many years.

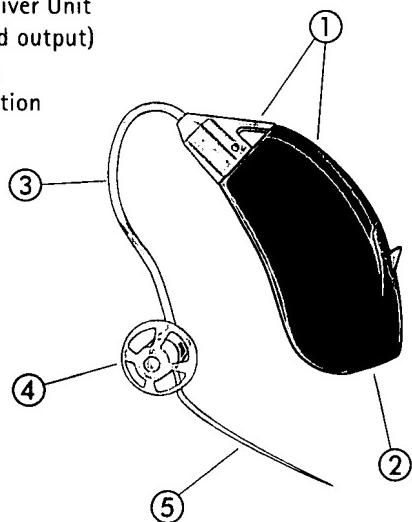
If you want additional information about microSavia Art CRT, please visit the Phonak website www.phonak.com.

Phonak – your partner for good hearing!

Description

microSavia Art CRT
with xReceiver and Dome for instant fit

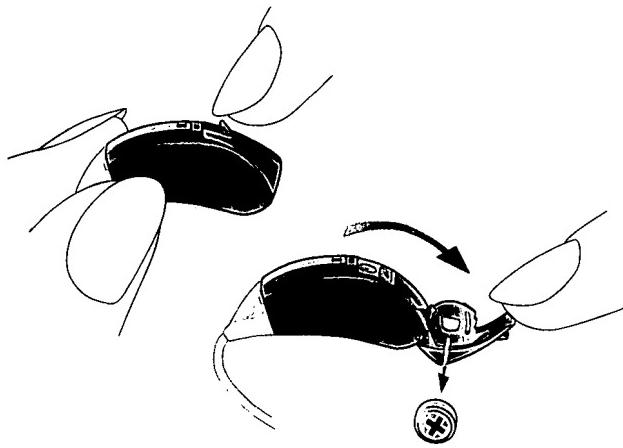
- ① Microphone inputs with Microphone Protector
- ② Battery compartment with ON/OFF switch (2 sizes: 312 standard, 10 option)
- ③ xReceiver Unit (sound output)
- ④ Dome
- ⑤ Retention



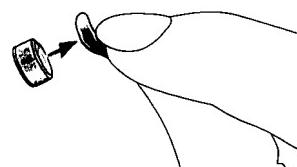
Preparation

Replacing the battery

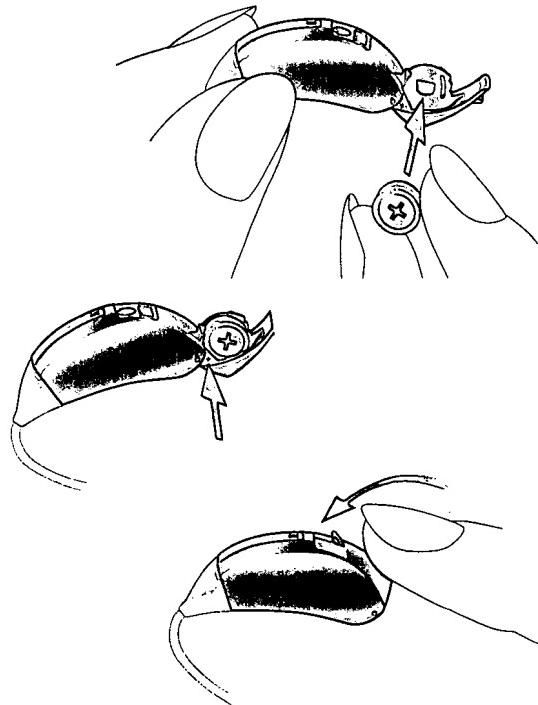
Using the nail grip, open the battery compartment completely and remove the old battery.



Remove the protective foil from the new battery.



Insert the new battery with the "+" sign (flat side of the battery) in line with the "+" marked on the battery compartment and close it.



Preparation

Replacing the battery

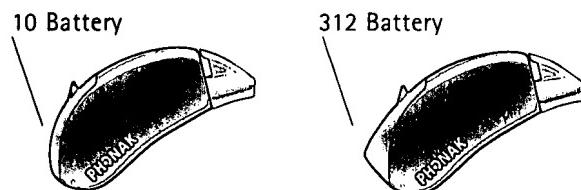
- ⚠ Handle the battery compartment with care, and do not use excessive force.
- ⚠ If there is any resistance when shutting the compartment, ensure that the battery is inserted correctly. The compartment may not close properly if the battery is upside down, and the instrument will not work.
- ⚠ When your hearing system is not in use, leave the battery compartment open to allow any moisture to evaporate.
- ⚠ We recommend to only use batteries which your hearing care professional approves and sells.

Low battery warning

An acoustic signal gives you an early warning that the battery is approaching exhaustion. Usually you have at least 30 minutes to replace the battery. With very high quality batteries, this reserve may be much higher and the hearing system will repeat the low battery warning approximately every 30 minutes.

Note:

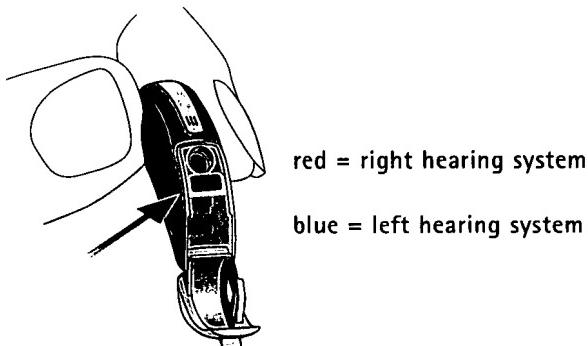
Your microSavia Art CRT hearing system offers the unique possibility to be operated either with size 312 (standard) or size 10 batteries (option). Your hearing care professional may modify the devices accordingly. The 312 battery lasts longer and is easier to handle, the 10 battery creates an even small overall instrument size (refer to picture below).



Identifying left and right hearing systems

It is important to use the correct instrument for each ear. Your hearing care professional can mark the instruments for you with a color code placed on the case under the nail grip of the battery compartment. The color code is visible when the battery compartment is opened. It will identify left and right instruments as follows:

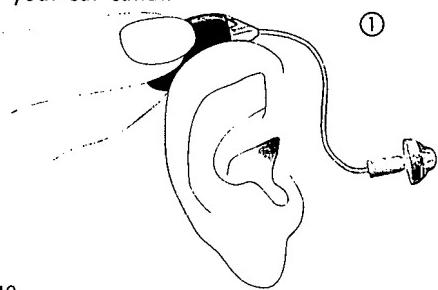
Preparation

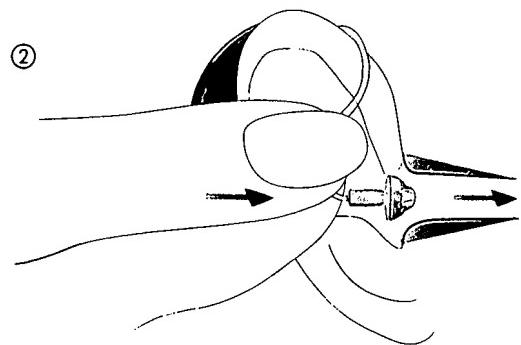


Inserting microSavia Art CRT with xReceiver and Dome into your ear

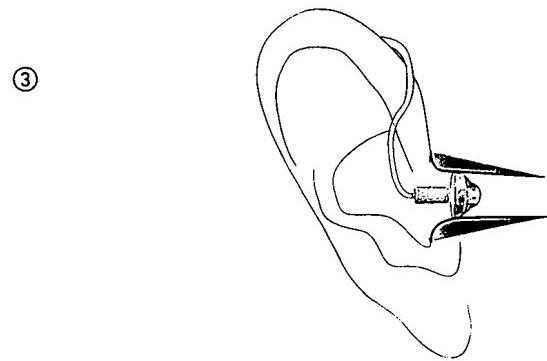
Open domes:

Hold the xReceiver Unit where it attaches to the Dome ① and gently push the Dome into your ear canal.





Place the hearing
instrument over the top
of your ear ②.



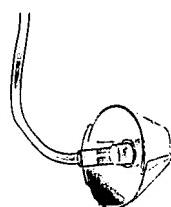
The Dome should be placed far enough into the ear so
that the xReceiver Unit lies flush with your head ③.

Preparation

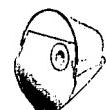
Closed domes:

The closed dome has a different design than the open dome, refer to picture. The closed dome consists of two fins overlapping each other. Before inserting the closed dome into the ear canal it is important to check the position of these fins. The bigger fin must be positioned over the smaller fin, see picture ④. If the position is incorrect ⑤, you can easily adjust it with one finger, just bend smoothly the bigger fin forwards and then back again so that it is overlapping the smaller one, see picture ⑥. Make also sure that the slit of the closed dome is in a horizontal position on the tube unit, as shown in picture ④. Your closed dome and external receiver unit is ready to be inserted into the ear, refer to page 10.

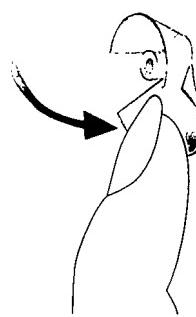
Correct position
④



Wrong position
⑤



Moving the fins
⑥



Preparation

Fine tuning based on your personal preferences

The fitting process has limited capabilities of reproducing the full spectrum of your personal sound environments. This limitation is now overcome by the ability of microSavia Art CRT hearing system to learn from your real life volume adjustments. microSavia Art CRT hearing system offers a unique functionality called "Self Learning". In every environment, it logs your personal volume changes within the hearing instrument. This means that every time you change the volume of your microSavia Art CRT hearing system, this correction is taken into account to apply your preferred volume automatically when you are in a similar environment next time.

Self Learning cleverly ensures that your volume corrections in each environment contribute to a fully personalized volume setting.

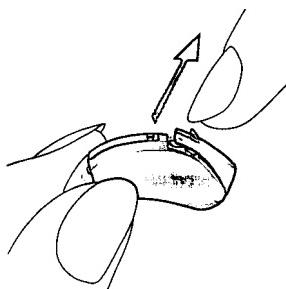
To fully benefit from this Self Learning feature, please ask your hearing care professional to demonstrate to you the available remote controls for your hearing system.

Operation

Switching ON/OFF

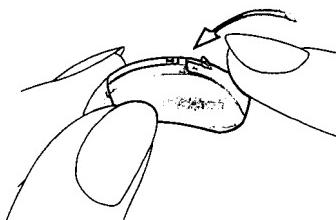
Switching OFF

Using the nail grip,
slightly open the battery
cover until it snaps into
its OFF position.



Switching ON

Close the battery
compartment
by pressing on
the base of
the instrument.



Your hearing care professional may have delayed the start-up of your microSavia Art CRT hearing system (9 or 15 seconds once it is switched on), in order to avoid any disturbance when placing it on your ear. The start-up is confirmed by an acoustic signal.

Operation

Telecoil (T-coil):

Your hearing care professional may have activated a T-coil program in your microSavia Art CRT hearing systems.

The programs with T-coil are used with telephones that are compatible with hearing systems or with inductive loop systems (present in some school settings, theatres, churches, etc.) as well as other wireless solutions (e.g. Phonak MyLink FM system).

You can activate the T-coil program with the remote control.

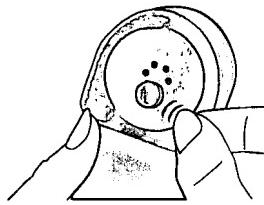
EasyPhone^{plus} (optional)

The EasyPhone^{plus} function enables your microSavia Art CRT hearing system to automatically select your telephone program when the telephone handset is held close to your ear. An acoustic signal confirms the switching.

It automatically returns to the previous hearing program when the telephone handset is removed from your ear.

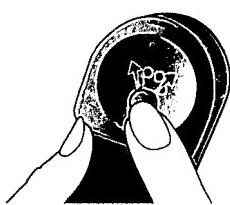
Some telephones produce a magnetic field strong enough to activate your EasyPhone^{plus} function. Most types of telephones require an additional magnet fixed on the handset to activate this function.

Fixing the EasyPhone^{plus} magnet



Clean the telephone handset thoroughly.
Hold the telephone handset nearly vertically, similarly to making a telephone call. Hold the magnet near the "listening end" of your telephone handset and release it.

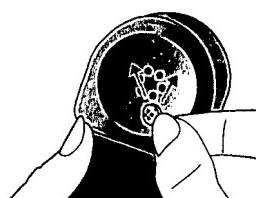
Operation



If you hold the telephone receiver in your right hand when making telephone calls, position the magnet in the upper right half of the receiver.

If you hold the telephone receiver in your left hand when making telephone calls, position the magnet in the upper left half of the receiver.

Use the double-sided adhesive tape to stick the magnet to the location described above. Do not cover the sound openings of your handset.



Use of EasyPhone^{plus}

Use the telephone in a normal manner. An acoustic signal indicates the activation of the EasyPhone^{plus} program. At the beginning, you may need to move the handset slightly to find the optimum position for a reliable switching and comfortable hearing.

If necessary, move the magnet to another position on the handset to increase your comfort of use.

- ⚠ Keep magnets out of reach of children and pets.
If a magnet is swallowed, please seek the advice of a medical practitioner.
- ⚠ The magnet used to strengthen the magnetic field of your phone may affect some medical devices or electronic systems.
Always keep the magnet (or the telephone equipped with the magnet) at least 30 cm (12") away from pacemakers, credit cards, floppy disks or other magnetically sensitive devices.
- ⚠ Too high distortion during dialing or phoning may mean that the phone receiver is stressed by the magnet. To avoid any damage, please move the magnet to another place on the telephone receiver.

Operation

Remote control (optional)

Remote controls from Phonak allow for discreet and convenient control of all the functions of your microSavia Art CRT hearing system:

- Volume up
- Volume down
- Program changes

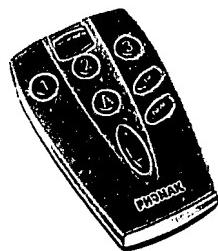
If you wear two microSavia Art CRT hearing instruments, the remote control will simultaneously control both of them. This ensures that their volume remains binaurally balanced.

Phonak offers a complete range of modern remote controls. Ask your hearing care professional to demonstrate them to you. Choose the model that is most convenient for your lifestyle and your taste.

WatchPilot2: exclusive and modern, available for women and men, with sporty rubber band or elegant metal band. Also recommended for MyLink users (Wireless System)

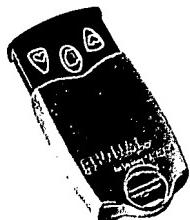


SoundPilot2: direct access to all functions of your microSavia Art CRT hearing system.
Also recommended for MyLink users (Wireless System)



Operation

KeyPilot2: small, easy and convenient.



For best results with your KeyPilot or WatchPilot
remote control, refer to the photo.

For detailed information on the use of your remote control, please refer to its user guide. Your hearing care professional can also print an individual description of your hearing programs for you.

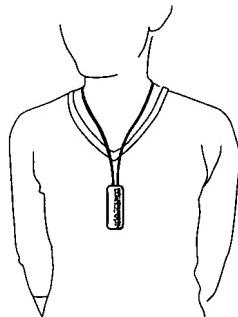
 **Do not use your remote control in locations where it is forbidden to use electronic devices, for instance on airplanes.**

Wireless Systems – MyLink (optional)

Your microSavia Art CRT hearing system allows you to fully benefit from the Wireless Systems from Phonak.

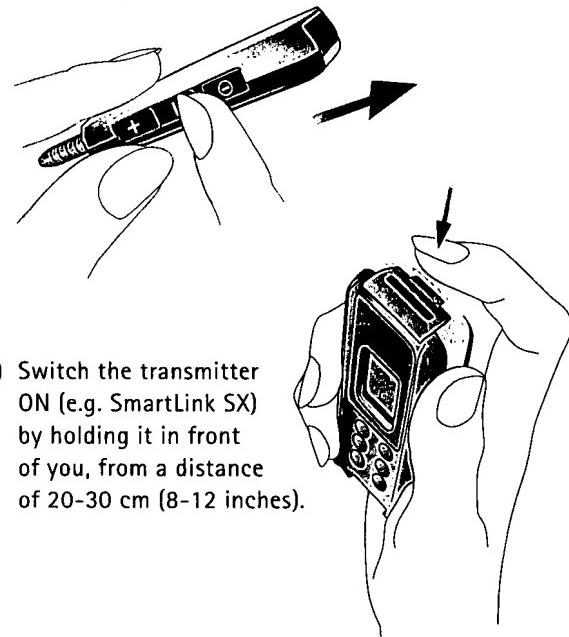
Wireless Systems greatly improve communication when noise, distance or reverberation is a problem. A Wireless System consists of a transmitter (e.g. SmartLink SX or EasyLink) and a receiver (MyLink). The transmitter is placed near the sound source. It may also be directly connected to your TV set, radio or telephone or linked via Bluetooth to your mobile phone. The signal is transmitted wirelessly via the MyLink receiver to your microSavia Art CRT hearing system.

The MyLink receiver
can be worn over
or under your clothes.



Using MyLink

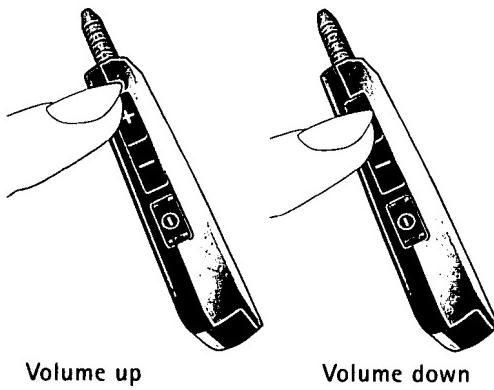
- 1) Wear MyLink around your neck
- 2) Switch MyLink ON



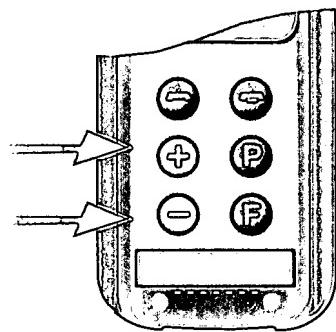
Wireless Systems – MyLink (optional)

The transmitter automatically selects the telecoil and microphone program of your microSavia Art CRT so you can hear the voice picked up by the transmitter and the voice picked up by the hearing system's microphone.

- 4) Your Wireless System is now ready to operate.
To increase/decrease the volume of the wireless signal, use the MyLink volume control.

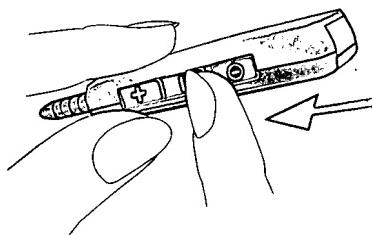


For SmartLink users: To increase/decrease the volume of the microSavia Art CRT system, press here:



Please consult the SmartLink SX or EasyLink User Guide to fully benefit from your Wireless System in all the different use cases.

- 5) Switch MyLink OFF



Maintenance

The wax system on your tube external receiver

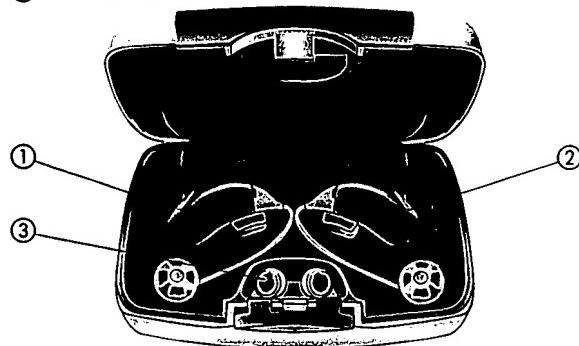
The external Receiver unit has an exchangeable Cerustop wax system. Only this system shall be used. Contact your hearing care professional for more information.

Protective case

Phonak developed a special protective case to securely store your hearing system, batteries and accessories.

Store your microSavia Art CRT hearing system in its protective case when not in use and leave the battery compartment in the OFF position (as described on page 15) to allow any moisture to evaporate. Remove the batteries if you will not be using your hearing system for any length of time.

- ① Left hearing system
- ② Right hearing system
- ③ Batteries

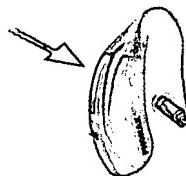


Maintenance

Microphone Protector

Important: The Microphone Protector is an exclusive Phonak system designed to protect the microSavia Art CRT high-tech microphones from dirt. The Microphone Protector can be replaced if needed. Your hearing system should not be used without the Microphone Protector.

Your hearing care professional can tell you whether the Microphone Protector should be exchanged or not.



Important: Consult your hearing care professional about changing the Microphone Protector if you experience any of the following:

- The hearing system sounds quieter than usual.
- There is a reduction in sound quality.
- Understanding in noise becomes more difficult.
- It becomes more difficult to determine the direction of sounds.

Important points

- 1) Always use new batteries as replacements.**
You can return empty batteries to your hearing care professional.
- 2) Protect your hearing system from excessive moisture and heat.** Always remove your hearing system before showering, bathing or swimming.
Do not leave your hearing system near windows or in a car. Avoid strong jolts and vibration.
- 3) Daily cleaning and the use of a drying system is highly recommended.** We recommend CleanLine from Phonak to care for your microSavia Art CRT hearing system. Your hearing care professional will gladly advise you. Never use household cleaning products (washing powder, soap, etc.) to clean your hearing system.

Maintenance

- 4) Hair spray, face creams and make-up can damage your hearing system. Remove the instruments before applying cosmetics.
- 5) If you experience any soreness or inflammation in or behind your ear, contact your hearing care professional.
- 6) If your hearing system fails to operate after you have correctly inserted new batteries, contact your hearing care professional for advice. Please remember to also bring your remote control, if you use one, together with your hearing system for service inquiry.



The symbol with the crossed out disposal bin indicates that this hearing instrument shall not be treated as household waste. Please hand over your old or unused hearing instrument to the applicable collection point for the recycling of electrical and electronic equipment or bring your old hearing instrument to your hearing care professional for appropriate disposal. By ensuring this product is disposed of correctly, you will help prevent potential negative effects on the environment and human health.

Warning

- ⚠ Hearing systems batteries are toxic when swallowed!**
Keep them out of reach of children and pets. If batteries are swallowed, please seek the advice of a medical practitioner!
- ⚠ Use only hearing systems that have been specially programmed for you by a hearing care professional.** Other instruments may be ineffective and may, in certain cases, even damage your hearing.
- ⚠ X-ray radiation (e.g. CT scans, MRI scans) may adversely affect the correct functioning of your instruments.** We recommend that you remove them before undergoing X-ray procedures and keep them outside the room.
- ⚠ Hearing systems in directional microphone mode (dSZ) reduce mainly background sounds.** Warning signals coming from behind and vehicles' horns approaching from behind are partially or completely suppressed.

Service and Warranty

Phonak offers you a comprehensive global warranty which becomes effective on the date of purchase. Please ask your hearing care professional about the details and duration. This warranty covers any repairs due to defects in material and/or workmanship. The warranty does not cover damage from improper handling or care, exposure to chemicals, immersion in water or undue stress. Damage caused by third parties or non-authorized service centers renders the Phonak warranty null and void. This warranty does not include any services performed by a hearing care professional in his office.

This warranty applies to the Phonak products listed below:

Serial numbers:

Instrument – right:

Instrument – left:

Date of purchase:

Phonak distributors worldwide

Group companies:	(detailed information on www.phonak.com)
Australia	Phonak Australasia Pty. Ltd. Baulkham Hills N. S. W. 2153
Austria	Hansaton Akustische Geräte GmbH 5020 Salzburg
Belgium	Lapperre N.V., 1702 Groot-Bijgaarden
Brazil	CAS Produtos Médicos São Paulo - SP 04363-100
Canada	Phonak Canada Limited Mississauga, Ontario L5S 1V9
China	Phonak (Shanghai) Co. Ltd., Shanghai City 200233
Denmark	Phonak Danmark A/S, Nitivej 10 2000 Frederiksberg
France	Phonak France SA, 69500 Bron
Germany	Phonak GmbH, 70736 Fellbach-Oeffingen EC Representative
Italy	Phonak Italia S.r.l., 20159 Milano
Japan	Phonak Japan Co., Ltd., Tokyo 101-0044
Jordan	Phonak Middle East, 11181 Amman
Netherlands	Phonak B.V., 3439 ME Nieuwegein
New Zealand	Phonak New Zealand Ltd., Takapuna Auckland 9
Norway	Phonak AS, 0105 Oslo
Poland	Phonak Polska Sp. z o.o., 00-567 Warszawa
Spain	Phonak Ibérica S.A., 03008 Alicante
Sweden	Phonak AB, 117 43 Stockholm
Switzerland	Phonak AG, Phonak Schweiz, 8712 Stäfa
United Kingdom	Phonak UK Limited Warrington, Cheshire WA1 1PP
USA	Phonak LLC, Warrenville, IL 60555-3927

**Independent
general agents:** A complete list of Phonak distributors is available at Phonak's Internet site: www.phonak.com. Please visit us or ask your hearing care professional for information.

Manufacturer: Phonak AG, Laubisrütistrasse 28
CH-8712 Stäfa, Switzerland



The CE symbol is confirmation by Phonak AG that microSavia Art CRT products and accessories meet the requirements of directive 93/42/EEC on medical devices.



This symbol indicates that microSavia Art CRT products comply with requirements for a BF type applied part according to EN 60601-1.

Safety notice External devices may only be connected if they have been tested in accordance with corresponding IECXXXX standards. Only use accessories approved by Phonak AG.

Operating conditions The hearing system has been designed for trouble-free operation under all ordinary climatic conditions.

Transportation and storage conditions Temperature should not exceed limits of -20°/60° Celsius at a relative air humidity of 65% for extended periods during transportation and storage. Air pressure between 500 and 1100 hPa is not detrimental to the instrument.

Your hearing care professional:

www.phonak.com

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

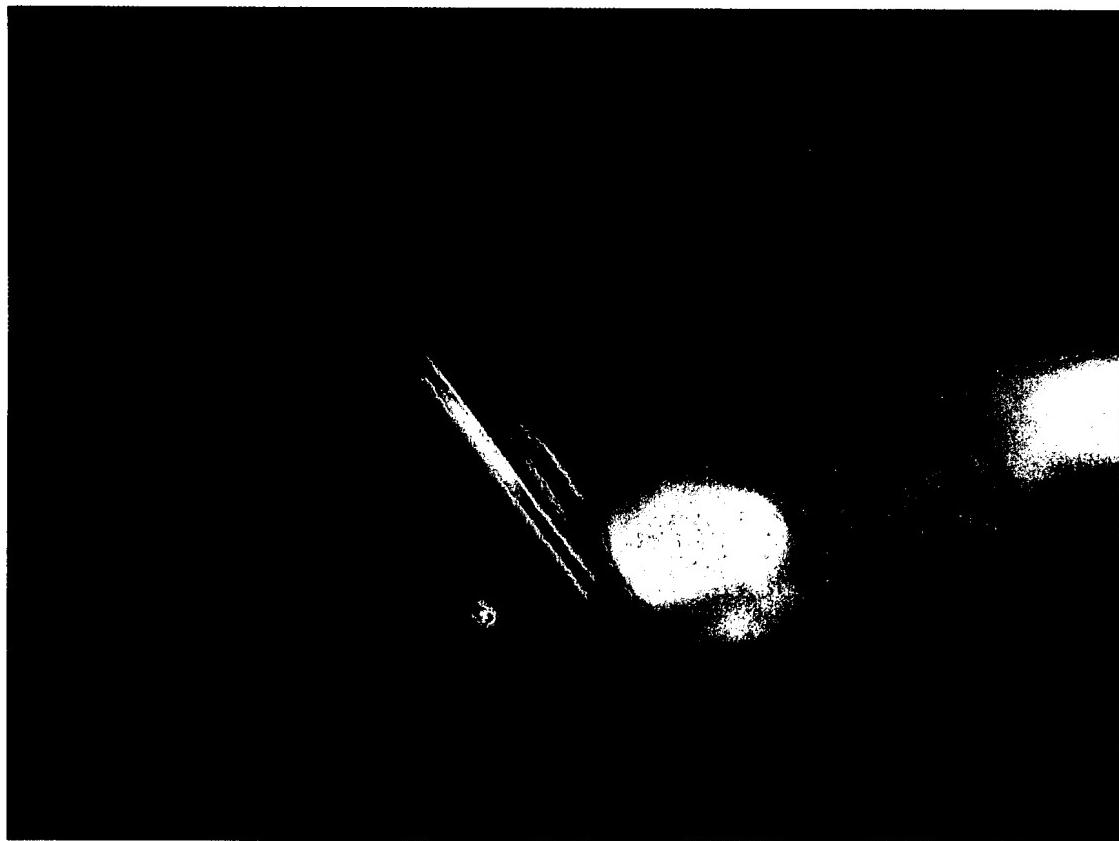
DECLARATION UNDER 37 CFR 1.132

Sir:

Charles I. Berlin, Ph.D. declares and says that:

1. My Curriculum Vitae is attached hereto at Exhibit 1. The contents of the CV illustrate that I am an expert in the field of Audiology and hearing physiology. I served as Director of the Kresge Hearing Research Laboratory at LSU Medical School for 40 years and brought its affiliated clinic to a level in which it was described in a popular magazine as "The Best Place to Come in America for Hearing Problems". We held continuous NIH funding for almost all of those years and when I retired, grateful patients and colleagues endowed a \$1 Million Chair in my name called "The Charles I Berlin Chair in Hearing Science".

2. I am familiar with Vivotone's open ear hearing aid system and when it was first brought to my attention I could see immediately that it had the potential to be revolutionary in the hearing aid industry.
 - a. In order to fully understand the nature of my enthusiasm, I would first like to digress into critical descriptive terminology that may not have been available to the examiners. We must first clarify the differences between insertion loss, insertion gain and occlusion effect which may have been confused by examiners who were not entirely familiar with the field's sometimes arcane terminology.
 - b. All of the measures described below are acquired with the use of a probe microphone, placed in the ear canal, with servo-controlled sound levels being presented to the ear of each individual patient. See Figures 1-3. Figure 1 below shows a probe microphone in place with a paper clip showing the direction of the thin plastic tube that goes 17 mm into the ear canal.



- c. FIRST the ear canal's acoustic characteristics must be measured with NOTHING in the ear (The Real Ear Unaided Response). A sample curve is in Figure 2. Figure 2 below shows that, with a servo controlled 40 dB input at the edge of the ear canal, the unoccluded canal imparts a 16 dB resonance of its own at 3000 Hz.
- d. Then insertion loss is acquired by comparing the sound in the ear canal when there is nothing in the ear vs. with a device in the ear BUT TURNED OFF. See Figure 3. Figure 3 below shows the open ear response on the left compared to the Vivotone and Sebotek devices, both "open fit" hearing aid in place, but turned off. The ideal response for purposes of open fit is a straight "difference line" at 0 dB. That is to say that the open ear response and the insertion loss response are as close to identical as possible.

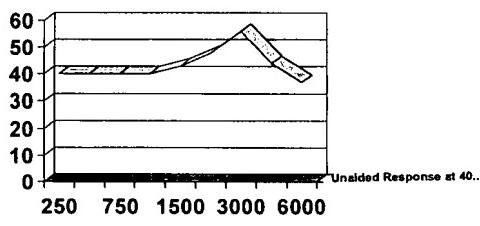


FIGURE 2
Real Ear Unaided Response
(REUR)

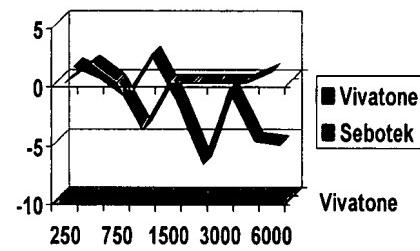


FIGURE 3
Insertion Loss Relative to REUR
Any deviation in either direction from 0 is undesirable

- e. The unaided response usually has a resonance peak in most adult ears between 2500 and 4000 Hz.
- f. Insertion loss is usually expressed in dB of obstruction caused relative to that unaided response.
- g. The Vivotone system caused virtually NO obstruction in repeated experiments completed in my lab in New Orleans in March of 2004; these data were presented at the Vivotone booth of the AAA convention on April 1st and 2d, 2004. (Unfortunately Hurricane Katrina may have claimed them but I have repeated the experiment above.)
- h. This device also has virtually no Occlusion Effect. The Occlusion effect stems from virtually complete filling of the external canal in such a way as to allow bone conducted sound from the floor of the external canal to be forced into the ear drum membrane. The effect causes users to sound like they are in a barrel. An example is under separate cover which is from one of the books I edited called Hair Cells and Hearing Aids. The demonstration was prepared by Dr. Mead Killion, arguably one of the best hearing aid engineers-cum-audiologists in our field. The occlusion effect can be minimized by a number of maneuvers (i) inserting a receiver deep into the canal past the mandibular process which forms the floor of the ear canal, (as in Feeley 09/927,981) or (ii) using open or vented ear molds.
- i. **BOTH OF THESE ABOVE MANEUVERS USUALLY CAUSE A MEASURABLE INSERTION LOSS.**
- j. Insertion GAIN is the relative difference between the unaided response (REUR) and the output of the hearing aid WHEN IT IS ACTIVATED. This obviously changes with the intensity of the signals and the signal processing built into the hearing aid. To measure Insertion Gain, the hearing aid must be turned on. To measure Insertion Loss the hearing aid must be turned OFF but in place. Thus Insertion Loss is static and DOES NOT CHANGE WITH THE LEVEL OF INPUT. Insertion Gain CAN DROP TO ZERO AT HIGH SOUND PRESSURES ONLY WHEN THE AMPLIFIER IS EXERTING A COMPRESSION

FUNCTION. In any event, Insertion Loss and Insertion Gain cannot be considered the same.

- k. However, decibels are relative logarithmic numbers*. Thus, because the log of 1 is Zero, whenever the numbers generated in the ear canal are identical in the two conditions (unaided vs. aid in place but turned off), there is a ratio of 1:1 between the reference measurement and the obtained measurement. That 1:1 ratio is the IDEAL Insertion Loss, and approaches zero in the measurements I have personally made on the Vivotone devices.¹
 - l. It should be stressed that Insertion Loss and Occlusion effect are two entirely different issues, although they are related to the mechanical status of the external canal.
 - m. Occlusion effects should be avoided because they cause discomfort to the patient.
 - n. Insertion losses are another story. Because many patients have segments of their hearing curve which are normal, it is useful to allow those segments to reach the ear drum membrane without obstruction. Thus minimal insertion loss is desirable because the hearing aid need only amplify (and/or potentially distort) those portions of the spectrum, which the patient can't hear naturally.
 - o. Thus the Vivotone device has virtually no insertion loss and no occlusion effect because of the open coupling to the ear, but the two effects are not to be considered one and the same.
3. The Vivotone configuration includes a behind-the-ear amplifier and a receiver suspended within the ear canal in an open ear configuration. This configuration is different from the other hearing aid configurations. Hearing aids may be broken down into various categories, including completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids.

¹ $\text{dB} = 20 \times \log \frac{\text{Output}}{\text{Reference}}$ Thus when output = reference or in this special case when the unaided response and the insertion loss are identical, the fraction becomes "1" and the log of 1 is zero. Zero dB therefore does not mean absence of sound, but only no difference between two sounds in a relative scale in which one sound is compared to another. I could find little or NO insertion loss in the Vivotone and thus the "less than three dB claim" should be modified.

Certain (but not all) BTE devices are “open fit” devices, which route a tube from a speaker behind the ear into the ear canal. The tube is intended to be non-occluding and thus cause minimal insertion loss. The Vivotone system is a new category of these “open fit” devices, and appeared to me to be revolutionary with regard to the prior BTE tube devices and all other categories of hearing aids.

4. Benefits of the Vivotone device relative to the other categories arise by nature of the open, suspended speaker in an open canal connected to the small BTE. Resonance effects of the tube design are eliminated, but the open fit is retained. Use of the BTE with all components but the speaker allow for this open fit. Feedback problems are also minimized by the placement of the microphone behind the ear.
5. Vivotone appeared to me to be the first company to introduce this product and when I first saw the product in 2004, I felt that it would change the industry. Phonak, Siemens, Interton, Oticon, and Hansaton seem to me to have subsequently copied Vivotone’s essential configuration. While various versions of these devices may have different or additional features, they have all taken Vivotone’s essential design (which design I considered and still consider revolutionary), including the small BTE with the microphone port, the thin speaker connecting wire, and the small speaker suspended in the open ear canal. (See Figure 3, which compares the Insertion Loss of the Sebotek to the Vivotone aid.)
6. It is also my understanding that the Patent Examiner has rejected the claims with regard to U.S. Patent Number 5,987,146 to Pluvinage. Specifically, the Examiner states that the Pluvinage patent teaches that one possessing ordinary skill in Audiology would be motivated and able to modify the hearing aid described by Pluvinage such that the Vivotone configuration would result. Pluvinage requires both a speaker in the ear canal and a sound sampling tube (alongside the speaker) within the ear canal. This configuration significantly occludes the canal relative to the Vivotone configuration, and unlike Vivotone, suffers from tubal resonance effects. In light of Pluvinage’s teachings,

however, it would not be obvious simply to remove the sound sampling tube. Pluvinage required the sound sampling tube to control feedback and make its own probe mike measures. One possessing ordinary skill in the art would look at the benefits and drawbacks of Pluvinage's design in light of conventional BTE-tube and BTE-mold devices and either accept or reject the design. One possessing ordinary skill in the art of Audiology would also not be motivated to make a change to avoid patent infringement and one possessing ordinary skill in Audiology would not likely be a lawyer and would not know how to analyze an infringement problem.

7. It is also my understanding that the Patent Examiner believes that Figure 11 of U.S. Patent to Pluvinage and the description of "insertion gain" on Column 8, lines 15-26, equally describe the "insertion loss" aspects of Dr. Bauman's claims. This is an error. The examiner has understandably missed the subtle but essential difference between Insertion Loss and Insertion Gain. As noted above, Dr. Bauman speaks to "insertion loss" rather than "insertion gain." The examiner's interpretation of Pluvinage's Figure 11 may have been initially confused by the fact that insertion GAIN and insertion LOSS are BOTH measures taken relative to the REUR (unaided open ear) in Figure 2. This is true. But the GAIN measure is taken when the hearing aid is turned on, where the LOSS measure is taken when the device is turned off (see Figure 3). Thus it is quite possible for a device to have 0 dB Insertion Gain at high intensities, but always have measurable or significant Insertion Loss at any intensity.

8. Following our meeting with the examiners on February 27th 2007, I compiled the following rebuttals to meet the objections raised by the examiners:

- a. The examiner felt that it would be obvious to simply remove tube 32 from the Pluvinage device resulting in the Vivatone device. In numerous places throughout the Pluvinage application it is repeated that BOTH tubes are required, one to record ambient sound through the resonance peaks of the ear canal and the other to bring sound from the processor (described later as a multiband compressor

which was the ReSound device in practice) to the speaker or receiver in the ear canal.

- b. The purpose of the second tube was essential to the device's multipurposes...to use the ear's natural resonances to shape and color the incoming speech, to use the microphone in the ear to sense and correct for feedback, (section 8 lines 27-39 and elsewhere)...and to receive and compare a plurality of signals (Column 7 Lines 6-16). All of this speaks to the examiner's suggestion that the second microphone and/or tube could be removed with no real changes to the device. This is clearly not supportable by data.
- c. The Examiner discounted the contents of the processor as being "unknown". In fact it was clearly described in the text as a Wide-dynamic range compressor (See Columns 6 lines 48 to 67: Column 7 lines 6 –16), which I recognize to be a ReSound™ hearing aid, ubiquitous in the early 90s as the best device available for ordinary sensori-neural loss.
- d. The adaptations required of the processor were IMPOSSIBLE without the use and presence of the second sound tube. This sound tubes creates a servo-system connecting microphone to processor to speaker or receiver and smoothing and/or feedback reducing the entire frequency response.
- e. In summary, the device would not work as intended without the second tube.

9. I also understand that the Examiner believes that the Knowles EH or FK series speakers describe certain "maximum lateral dimension" limitations of Dr. Bauman's claims (taken together with the teachings of Pluvinage). Pluvinage does teach a speaker (part of a receiver) in the ear canal. The Pluvinage receiver would also include a housing material provided around the metallic speaker case. While we know the Knowles speaker size, the Pluvinage document does not indicate how thick the receiver plus the housing material would be. Additionally, because the microphone sampling tube is placed side by side with the receiver, the "maximum lateral dimension" of the setup would exceed the limitations of Dr. Bauman's claims (i.e., more than 50 percent of a lateral dimension of most patient's ear canals). The larger the device in the ear canal the more likely it is to

cause insertion loss. The more contact it has with the bony walls before the bony meatus, the more likely it is to cause an insertion loss as well as an occlusion effect.

10. I also understand that the Patent Examiner has indicated that one possessing ordinary skill in Audiology would be motivated to change the CIC device described by U.S. Patent Application Number 20040010181 to Feeley. I disagree. Feeley always requires an occluding or partially occluding mold (though the mold may be vented). The “open mold configuration” described by Feeley is a vented mold. This is not (and does not suggest) the essential Vivatone configuration. Feeley does not describe suspending a speaker in the open ear canal in any way, the ear canal is not open, and the term “open mold” merely describes a mold vent. The Feeley device, even if disconnected from the original housing as the examiner suggests, could not approach the “open-ness” of Vivatone in terms of Insertion Loss. Data to prove this prediction can be inferred from Figure 3. The Examiner also believes that the eartip (described in U.S. Patent Application Number 2003002700 to Fretz at number 14 in the drawings) of Fretz would be usable around the speaker of Feeley. Fretz describes a conventional BTE-tube design, and Feeley requires a mold. These configurations would cause much more insertion loss than the Vivatone.

11. I also understand that the Examiner discredits the value of the commercial success evidence (see Mr. Hirsch’s Declarations). I have stated that I thought the Vivatone product was revolutionary and by that token could soon change the way hearing aids are made and distributed. One of its greatest features is that you can walk in to a provider’s office, and if you are a candidate for this device, you can walk out with a fully programmed perfectly fit hearing aid which requires no earmold, no waiting and little readjustment.

It also serves as an excellent emergency hearing aid for travelers who have lost or broken their aids etc. This is not an inconsequential issue and is another of the major values of this device and its fitting. This also applies to tube design devices but they are likely to have more insertion loss

In the end the Vivotone is simply not comparable to other devices because of its unique construction, ability to handle both insertion loss and occlusion problems, and be versatile and flexible enough to fit a patient without special customized ear molds or shells etc.

It appears as if Vivotone lost market share when the competitors copied Vivotone's instrument, but Vivotone's success in the industry was impressive, particularly because Vivotone spent very little on advertising and had no broad name recognition in the industry. Most small companies fail for those same reasons. I disagree with the Examiner's discrediting of the commercial success evidence for lack of foresight and understanding of the industry's issues. At present "open canal fits" are among the hottest new recommendations in the marketplace.

12. The Patent Examiner has indicated "hearing aids are not the type of device you see advertised on TV or in popular magazines." He also indicated that hearing aids are distributed in a controlled manner (much like selling blood pressure or cholesterol lowering medication). This is not altogether true. The "controlled nature" means that licensed professionals (audiologists and hearing aid specialists and physicians) can dispense hearing aids. But they can also be sold over the internet and by mail order houses.

Advertising in the hearing aid industry directly affects sales, as per ads for many years for Miracle Ear on CNN during the Gulf War and similar TV ads for Beltone and Siemens. Vivotone's commercial success was driven by word-of-mouth referral and was phenomenal (despite minimal advertising). It should not be discounted.

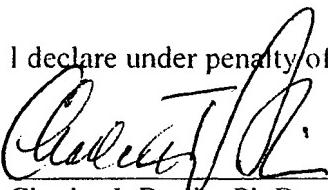
13. With regard to the Patent Examiner's comments on market data, the Examiner compares Vivotone's sales relative to certain categories (0.65% of all hearing aid sales; 1.78% of all BTE units). He also references an article by Kirkwood in the Hearing Journal in which GN ReSound CEO Alan Dozier states "...with all the performance improvements, the question is, why do we continue to get 2%, 3% and 4% growth?" As I stated before, the revolutionary nature of the Vivotone system does not allow for

comparison with conventional designs (even with "open fit" tube designs, which are a subcategory of the BTE category). The Patent Examiner also indicates that the Vivotone system's success may be attributed merely to "exploratory success", or curiosity of the consumer, rather than to a "got to have it type of success." I disagree. Audiologists and dispensers with foresight who also did Real Ear Measurements could see immediately the unique value of these instruments.

14. The Examiner quoted a comment of Alan Dozier from GN Resound: "Not a lot of consumer advertising is being done to build confidence in hearing instruments and build brand awareness." This dated comment does not relate to this new category of hearing aids. The advertising of Oticon, Siemens, Hansaton, Interton and Phonak with regard to this revolutionary design is directly reflective of this industry change.

15. In summary what makes Vivotone unique to me is that it handles Occlusion Effects and Insertion Loss with the same speaker-in-the-ear non obtunding design. Devices produced since then are basically copies that do not work as well, and devices supposedly patented before Vivotone do not directly address the problems of Occlusion and Insertion loss separately in the creative manner exemplified by Vivotone.

I declare under penalty of perjury that the foregoing is true and correct.



Charles I. Berlin, Ph.D

March 13, 2007

EXHIBIT 1

Rev. April 2006

CURRICULUM VITAE

CHARLES I. BERLIN

Marital Status: Married, to Ms. Harriet Levin Berlin, 04/20/58, 4 children,
9 grandchildren

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FAX: 813-926-2136

E-Mails: cberli@lsuhsc.edu cberlin@cas.usf.edu

Education:

S. J. Tilden High School, Brooklyn, New York. 1950

New York University School of Arts and Sciences, Majors in Meteorology (School of Engineering),
English (School of Arts), Minors in Sociology, Speech, B.S. Degree. 1953

University of Wisconsin, Speech & Hearing, Minor in Psychology, M.A. Degree. 1954

University of Pittsburgh, Ph.D., Speech & Hearing, completed October, 1957, awarded January
1958.

U.S. Army Short Course for Psychologists, Letterman Hospital, San Francisco, CA, 1958.

Miami Medical Center, University of Florida, Short Course, Organic Voice and Speech Disorders,
1960.

Communication Sciences Seminars, University of Florida (Hearing Sciences), 1963.

Communication Sciences Seminars, University of Florida (Speech Sciences), 1964.

Speech Synthesis and Analysis Seminars, with G. Fant, University of Florida, 1966.

Medical Audiology Workshop, University of Colorado School of Medicine, 1966.

Research Career Development Award, 5K3 NB 19, 488, 1963-1967.

Special Post-doctoral Studies in Auditory Physiology, The Johns Hopkins Medical Institutions, 1963-1967.

Professional Status and Experience:

1952-1953 Meteorology Lab Assistant, School of Engineering, New York University, Bronx, New York.

1954-1957 Graduate Assistant, Research Assistant, University of Pittsburgh, Pittsburgh, PA.

9/57-1/58 Consultant, Brooklyn College, Community Speech & Hearing Clinic, Evening Division. Cerebral Palsy patients as primary caseload. High School teacher, New York City School System, Brooklyn, New York.

1/58-12/59 Military Service, Speech and Hearing Specialist, U.S. Army, Letterman General Hospital, San Francisco, CA. Speech Pathologist/Audiologist. Children and adult problems seen as a general caseload.

12/59-12/61 Audiologist and Speech Pathologist, USVA Hospital, San Francisco, CA. Laryngectomy and compensation patients as primary caseload.

1959-1961 Consultant in Speech and Hearing, May T. Morrison Center for Rehabilitation, San Francisco, CA. Aphasia and children's rehabilitation.

1959 Visiting Lecturer, College of Marin, Kentfield, CA. Speech Pathology - Stuttering.

1/62-6/63 Post-doctoral Fellow in Medical Audiology, The Johns Hopkins Medical Institutions, Baltimore, MD.

7/63-5/67 Research Career Development Award, 5K3 NB 19, 488 in conjunction with appointment as Assistant Professor, Laryngology and Otology, School of Medicine, The Johns Hopkins Medical Institutions, Baltimore, MD. Assistant Professor, Environmental Medicine, School of Hygiene, The Johns Hopkins Medical Institutions, Baltimore, MD.

- | | |
|---------------------|---|
| 9/66 | Advisory Scientist, Information Center for Hearing, Speech, and Disorders of Human Communication, The Johns Hopkins Medical Institutions, Baltimore, MD. |
| 6/67 | Associate Professor, Department of Otorhinolaryngology & Biocommunication; Director, Communication Sciences Laboratory, Louisiana State University Medical Center, New Orleans, LA. |
| 5/69-9/1/02 | Director, Kresge Hearing Research Laboratory of the South, Department of Otorhinolaryngology & Biocommunication, Louisiana State University Medical Center, New Orleans, LA. |
| 7/70-9/1/02 | Professor, Departments of Otorhinolaryngology & Biocommunication and Physiology, Louisiana State University Medical Center, New Orleans, LA. |
| 9/1/02-Present | Clinical Professor of Otolaryngology Head and Neck Surgery |
| April 2006 -Present | Research Professor Communication Sciences and Disorders, University of South Florida, Tampa FL |
| 7/70-9/1/02 | Clinical Professor, Department of Psychology, University of New Orleans, New Orleans, LA. |
| 1974-9/1/02 | Professor, Department of Communication Disorders, School of Allied Health Professions, Louisiana State University Medical Center, New Orleans, LA. |
| 3/75-9/1/02 | Audiology Consultant, Audiology and Speech Pathology Service, Veterans Administration Hospital, New Orleans, LA. |
| 1974-1979 | Coordinator, Self-Instructional Material Program (S.I.M.P.), Louisiana State University Medical Center, New Orleans, LA. |
| Spring 1975-1979 | Official Representative, Louisiana State University Medical Center, Association of American Medical Colleges, Department of Academic Affairs, New Orleans, LA. |
| 1/81-10/85 | Co-Director (with D. Mouney, M.D.) & Chief Audiology Consultant at Joachim Hearing & Speech Center, Eye and Ear Hospital of Louisiana. |
| 10/85-2002 | Director, Audiology Services, Department of Otolaryngology, Louisiana State University Medical Center, New Orleans, LA. |
| 8/30/98 | Kenneth and Frances Barnes Bullington Professor in Hearing Science. |

Professional Activities:

- 1963-1964 Editor, Maryland Journal of Speech and Hearing.
- 1963-1966 Associate Editor, Journal of Speech and Hearing Research.
- 1969-1972 Basic Science Member, American Academy of Otorhinolaryngology, Special Task Force for Revision of Board Examination.
- 1969-1972 Co-Examiner, American Speech & Hearing Association (one of three writers of ASHA Clinical Audiology Examination).
- 1972-1978 Member, American Academy of Ophthalmology & Otolaryngology, Committee of Video-Extension (COVE).
- Jan. 1973 Member, Louisiana State Board of Examiners in Speech Pathology and Audiology. Licensed in Audiology and Speech Pathology (License # 005).
- 1/73-2002 Member, NAS-NRS Committee on Hearing, Bioacoustics, and Biomechanics, National Research Council (CHABA).
- 2/73-1/77 Chairman, American Speech & Hearing Association, Scientific Affairs Committee.
- 4/75-1978 Member, Advisory Committee, Subcommittee on Self-Instructional Programs, American Academy of Ophthalmology & Otolaryngology.
- 2/76-1/79 Member, Graduate Council, Louisiana State University Medical Center; Executive Graduate Council, Louisiana State University System.
- 7/76-6/77 Vice-President and President Elect, Board of Health Sciences Consortium, Inc., Chapel Hill, North Carolina.
- 8/76-1/77 Secretary, Louisiana State Board of Examiners in Speech Pathology and Audiology.
- 7/77-6/78 President, Board of Directors, Health Sciences Consortium, Inc., Chapel Hill, North Carolina.
- 1978-1981 Member, Research Advisory Committee to the Deafness Research Foundation.
- 1978-2002 NINCDS/NIDCD Ad-Hoc Reviewer.

1983-1986	Member NIH-NINCDS-DRG Study Section BNS #4.
1986-1988	Vice-President for Educational & Scientific Affairs, American Speech-Language-Hearing Association.
1987-1989	Reviewer, Deafness Research Foundation.
1989-1994	Member, Advisory Board of the National Institute of Deafness and Other Communication Disorders.
1989-1990	Consultant to FDA on Cochlear Implants.
1993-9/1/02	Consultant to Hearing Industries Association
1999-2001	Consultant to Scientific Learning Corporation, Berkely, CA
2000-Present	Consultant to Sonus Corporation

Honors:

New York State Competitive Scholarship, 1950.

USPHS Travel and Training Awards, 1960, 1963, 1964, and 1966 (various workshops).

NINDB Special Fellowship, Medical Audiology, The Johns Hopkins Medical Institutions, BT-856, 1961.

ASHA NINDB Foreign Travel Award, International Congress of Audiology, 1962.

Research Career Development Award, 5K3 NB 19, 488, July, 1963.

Awarded First Place for Excellence of Presentation and Second Place for Scientific Merit by the American Speech & Hearing Association, Scientific Exhibit, "Topography of cochlear structures and the organ of Corti", November, 1969.

Fellow, American Speech & Hearing Association, 1969.

Full Member, Sigma Xi, 1969.

Awarded First Place for Scientific Merit by the American Speech & Hearing Association, Scientific Exhibit, "Relationship of structure to function in human and animal temporal bones", November, 1971.

Agnes B. Noyes Award for "Human Electrocochleography", grant from the Deafness Research Foundation, 1974, 1975.

Alfred P. Sloan Foundation, Facilitator Award, Health Sciences Consortium, 1975.

First Annual Scientific Achievement Award for Innovative Contributions to Audiological Science, Southern Audiological Society, 1975.

Certificate of Award for Distinguished Services, American Academy of Ophthalmology & Otolaryngology, October, 1976.

Outstanding Faculty Award for Presentation Excellence, 12th Colorado Otology/Audiology Workshop, Ltd., Vail, Colorado, March, 1978.

Chosen one of "83 to Watch in '83", New Orleans Magazine, 1983.

Recipient of the First Louis Di Carlo Award, September, 1983, for outstanding Clinical Contributions L.A.S.H.A., and Louisiana's Representative to the National Competition for 1983. Second DiCarlo Award for 1989 for outstanding clinical contribution to LASHA.

IHAS Distinguished Contribution to Hearing Research Award, 1984.

Distinguished Teaching Award for 1984 (Beltone) -- Cash Award and Scholarship for LSU.

Fellow, Acoustical Society of America, 1989.

Awarded First Place for Scientific Merit by the American Speech & Hearing Association, "Basic science and current audiological practice". Contributors: Berlin, C.I., Bobbin, R.P., Collins, M.J., Cullen, J.K., Jr., Hood, L.J., and Webster, D.B., 1989.

First Jerger Lecturer, Baylor College of Medicine, Houston, Texas, September 1993.

Presidential Citation, 1994, American Academy of Otolaryngology - Head & Neck Surgery, its highest award for teaching, research and science.

Frank J.Kleffner Award for lifetime clinical achievement from the American Speech-Language Hearing Foundation. 1994.

James F. Jerger Lifetime Career Research Award, American Academy of Audiology, April 1995. Its second recipient.

Carhart Memorial Lecturer, American Auditory Society, April 1997

Kenneth and Frances Barnes Bullington Professor in Hearing Science August 1998.

James P.Snow Award for Service to the Hearing Impaired Community from SHHH June 1999.

Robert B. Ruben MD Award from Society of Ear Nose and Throat Advances in Children (SENTAC) October 2000.

Honors of the Association, American Speech Language and Hearing Association, its highest award for research, clinical service and scholarship. November 2000.

Honorary Life Membership National Association of Future Doctors of Audiology (NAFDA) April 2003.

The \$1 Million Dr. Charles I. Berlin Chair in Genetic and Molecular Hearing Science was established in the LSU Department of Genetics by the Board of Regents in August 2004. This Chair, possibly the first of its kind to honor an audiologist and hearing scientist, was established by grateful patients, colleagues and friends who donated \$600,000 to LSU. The State Board of Regents matched this corpus with \$400,000, bringing it to its current level. A search is underway for a nationally recognized scientist to fill this position.

A similar chair, named after its Donors, Kenneth and Frances Barnes Bullington, is planned as a bequest towards The University of South Florida.

Society Affiliations:

Acoustical Society of America, Fellow

American Speech-Language-Hearing Association ,Fellow

American Association for the Advancement of Science

Greater New Orleans Society for the Neurosciences, President, 1973

American Association of Phonetic Sciences, 1973

American Academy of Ophthalmology & Otolaryngology, Associate Fellow, 1973

American Academy of Otolaryngology, Scientific Fellow, 1991

American Auditory Society, Charter Member, Member of the Executive Board, 1973, and current Life member.

Academy of Aphasia, 1974

Southern Audiological Society, Honorary Member, 1975

Association for Research in Otolaryngology, American Academy of Ophthalmology & Otolaryngology, 1975

American Academy of Audiology, 1988, Fellow.

Grants Management and Acquisition:

Continuous holder of 1 or more major Department of Defense or NIH Research Program Projects and/or Training Grants from 1963 to 1997, and recipient of funds from DRF and other private sources (Lions of Louisiana; Kam's Fund; LSU Foundation; Anheuser-Busch; McDonnell-Douglass; Kresge Foundation, Kleberg Foundation, et al.). Currently holder of Oberkotter Foundation and other private grants.

Administration and Committees:

Director of Kresge Hearing Research Laboratory of the South from its inception between 1967 and 1970 until September 1, 2002; President, Health Sciences Consortium; member of numerous University and professional committees; member of interdisciplinary committees between hearing scientists and clinicians, engineers, and philanthropists. Graduate Faculty Council 1975-1982. Member-at-large, LSU Faculty Council 1985-1986. Chair LSU-LCME Faculty Subcommittee for 1988 Accreditation Site Visit. Elected member, LSU Faculty Assembly, 1988. Chair, Community Relations Committee, LSU Professional Practice Association, 1989.

Teaching:

Advanced Clinical Audiology for Otolaryngologists and Audiologists - 48 courses in 39 years (1959-2000).

Basic Auditory Brainstem Response - 48 courses in 25 years (1975-2000).

Auditory Physiology or Neurophysiology - 18 courses in 19 years (1975-1997).

Neuroscience for medical students, dental students, etc. (Auditory section - 13 hours with Labs for LSU and Tulane University) - 58 courses in 28 years (1972-2002).

Real Ear Measurement in Hearing Aid Selection - 19 courses in 12 years (1988-2000)

Nova Southeastern University Advanced Auditory Physiology 3 courses per year including cohorts in London England, continuing through the present.

Teaching Materials:

See vita for programmed instruction devices on decibels, binary numbers, Ohm's Law, tympanometry and reflexes, annotated videotapes for clinical audiology, and training tapes. Books edited as part of

Mirmelstein/Kresge Award Series...5 of the 8 since 1996 contain Compact Discs with unique teaching material.

Legal and Legislative Experience:**Legal:**

Private Citizen vs. The Virginian. Richmond VA. Citizen was feigning hearing loss as a result of a cap pistol discharge in an elevator by the Television Star. Case decided in our favor.

Private Citizen vs. Nightclub. Citizen complained of Nightclub noise. Decided in our favor (citizen).

Eight local cases of noise encroaching on private property and/or audibilty of fire alarms, settled out of court.

Ad Hoc consulting for attorneys in class-action suit re: noise made by hand tools. Pending.

Deposition re: residual low frequency loss disabling a physician with respect to listening to heart and breath sounds. Decided in our favor (plaintiff-physician).

Deposition re: R.C. vs. Pensacola Fire Dept re: disabling tinnitus and hearing loss. Decided in our favor (RC).

Analysis of Audibility of Coast Guard Siren in Pass Manchac collision of tug and train trestle in the I-55 region of the pass.

Research and testimony on mild hearing loss and its need for hearing aids. For Major Car Rental Corporation, decided in our favor (HRC). 1998

School advocacy for my patients in due process hearings. Seven appearances, 4 decided in our favor.

Consulting for Hearing Aid Industry re: FDA regulations and their impact on hearing aid dispensing.

Legislative:

Political Action Contact for LA Delegation, 1980-2002

Support activities for New NIDCD (Deafness Institute)

Joining and supporting Family members and Associates lobbying on Capital Hill for various hearing related issues with Senators Harkin and Daschle, Vice-President Gore, and Representative Lindy Boggs.

Testimony re: Licensure, Louisiana State Legislature 1994-1996.

N.O. City Council re: Noise Ordinance and enforcement 1997.

Public Relations and Publicity:

Time Magazine, September, 1982
Discover Magazine, November, 1982
Nicolet Potentials, 1982
"Today Show", June, 1982
"That's Incredible", March, 1983
WTBS "Nice People", June, 1983
Times-Picayune (many articles), 1982-1994
New Orleans Magazine, 1983
Family Circle Magazine, October, 1987.

(Department selected as "America's Best Place to Come for Hearing Problems") Louisiana
Lions Annual Sight and Sound Telethon - currently Primary Host; previously pianist and co-host,
1979-1992.

NBC News "Otoacoustic Emissions", 1990.

New York Times, May >93 on issues related to Cochlear Implants, June >97 and again in 1998 and
1999 on issues related to genetic deafness among Ashkenazi Jews.

PUBLICATIONS

(Divided into Hearing, Speech and Voice, Books, Reviews, Educational Materials, Abstracts)

Hearing:

Berlin, C.I. Hearing in mice via GSR audiometry. *J. Sp. Hear. Res.* **6(4)**, 359-368, 1963.

Finck, A. and Berlin, C.I. Comparison between single unit responses in the auditory nerve and GSR
determined thresholds in mice. *J. Aud. Res.* **5**, 1-9, 1965.

Konigsmark, B.W., Berlin, C.I., Hollander, M.D., and McKusick, V.A. Study of familial
deafness-hearing loss associated with dermatitis. *Proc. Second Internatl. Cong. Neuro-Genetics
Neuro-Ophthalmol.* **1**, 809-812, 1967.

Mengel, M.C., Konigsmark, B.W., Berlin, C.I., and McKusick, V.A. Recessive early-onset neural
deafness. *Acta Otolaryngol.* **64**, 313-336, 1967.

Berlin, C.I., Gill, A., and Leffler, Martha. Hearing in mice by GSR audiometry: I. Magnitude of
unconditioned GSR as an index of frequency sensitivity. *J. Sp. Hear. Res.* **11(1)**, 159-168, 1968.

Eldridge, R., Berlin, C.I., Money, J.W., and McKusick, V.A. Cochlear deafness, myopia, and
intellectual impairment in an Amish family. *Arch. Otolaryngol.* **88**, 49-54, 1968.

Gill, A. and Berlin, C.I. Hearing in mice by GSR audiometry: II. Magnitude of unconditioned GSR as a function of intensity and frequency interaction. *J. Sp. Hear. Res.* 11(1), 169-178, 1968.

Konigsmark, B.W., Hollander, M.B., and Berlin, C.I. Familial neural hearing loss and atopic dermatitis. *J. Am. Med. Assoc.* 204(11), 953-957, 1968.

Eisenberg, L., Berlin, C.I., Dill, Anne, and Frank, S. Class and race effects on the intelligibility of monosyllables. *Child Dev.* 39(4), 1077-1089, 1968

Berlin, C.I., DiGiacomo, Elizabeth A., and Gill, A. Auditory screening of school children by volunteer mothers. *J. Sch. Health* 44(2), 95-101, 1969.

Berlin, C.I., Majeau, Deborah A., and Steiner, Sylvia. Hearing and vocal output in normal, deaf, and infant mice. *J. Aud. Res.* 9, 318-331, 1969.

Majeau-Chargois, Deborah A., Berlin, C.I., and Whitehouse, G.D. Sonic boom effects on the organ of Corti. *Laryngoscope* 80(4), 620-630, 1970.

Lowe, Sena S., Cullen, J.K., Jr., Berlin, C.I., Thompson, C.L., and Willett, Mary E. Perception of simultaneous dichotic and monotic monosyllables. *J. Sp. Hear. Res.* 13(4), 812-822, 1970.

Konigsmark, B.W., Mengel, M., and Berlin, C.I. Familial low frequency hearing loss. *Laryngoscope* 81(5), 759-771, 1971.

Berlin, C.I. and Lowe, Sena S. Temporal and dichotic factors in central auditory testing. Chapter 15 - Differential diagnostic evaluation: Central Auditory Function. Book Chapter in: Jack Katz (Ed.), Handbook of Clinical Audiology. The Williams & Wilkins Co.: Baltimore, Maryland, 280-312, 1972.

Berlin, C.I., Lowe-Bell, Sena S., Janetta, P.J., and Kline, D.G. Central auditory deficits after temporal lobectomy. *Arch. Otolaryngol.* 96, 4-10, 1972.

Berlin, C.I., Lowe-Bell, Sena S., Porter, R.J., Jr., Berlin, Harriet L., and Thompson, C.L. Dichotic signs of the recognition of speech elements in normals, temporal lobectomyees, and hemispherectomees. *IEEE Catalog No. 72, AFCRL 720120, Special Report No. 131*, Pp. 222-225, 1972.

Berlin, C.I., Lowe-Bell, Sena S., Cullen, J.K., Jr., Thompson, C.L., and Stafford, Marion R. Is speech special? Perhaps the temporal lobectomy patient can tell us. Letter to the Editor, *J. Acoust. Soc. Am.* 52(2), 702-705, 1972.

Cullen, J.K., Jr., Ellis, M.S., Berlin, C.I., and Lousteau, R.J. Human acoustic nerve action potential recordings from the tympanic membrane without anesthesia. *Acta Otolaryngol.* 74, 15-22, 1972 and 1973 Year Book of Ear, Nose and Throat, Pp. 16-18, 1973.

Berlin, C.I., Hughes, L.F., Lowe-Bell, S.S., and Berlin, Harriet L. Dichotic right ear advantage in children 5 to 13. *Cortex* **9**(4), 393-401, 1973.

Berlin, C.I., Lowe-Bell, Sena S., Cullen, J.K., Jr., Thompson, C.L., and Loovis, C.F. Dichotic speech perception: An interpretation of right-ear advantage and temporal offset effects. *J. Acoust. Soc. Am.* **53**, 699-709, 1973.

Berlin, C.I., Porter, R.J., Jr., Lowe-Bell, Sena S., Berlin, Harriet L., Thompson, C.L., and Hughes, L.F. Dichotic signs of the recognition of speech elements in normals, temporal lobectomyees, and hemispherectomyees. *IEEE Trans. Audio Electroacoust.* **AU-21**(3), 189-195, June, 1973.

Berlin, C.I., Cullen, J.K., Jr., Ellis, M.S., Lousteau, R.J., Yarbrough, W.M., and Lyons, G.D., Jr. Clinical application of recording human VIIIth Nerve action potentials from the tympanic membrane. *Trans. Am. Acad. Ophthalmol. Otolaryngol.* **78**, 401-410, 1974.

Lyons, G.D., Jr., Berlin, C.I., Lousteau, R.J., Ellis, M.S., and Yarbrough, W.M., Jr. Electrocochleography with retardates. *Laryngoscope* **84**(16), 990-997, 1974.

Berlin, C.I., Cullen, J.K., Jr., Lowe-Bell, S.S., and Berlin, H. Speech perception after hemispherectomy and temporal lobectomy. *Proc. Sp. Comm. Sem.* John Wiley & Sons: New York, New York, Pp. 9-15, 1974.

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Berlin, C.I. and Cullen, J.K., Jr. Dichotic signs of speech mode listening. In: A. Cohen and S. G. Nooteboom (Eds.), *Structure and Process in Speech Perception*. Proceedings of the Symposium on Dynamic Aspects of Speech Perception, held at I.P.O., Eindhoven, Netherlands, August 4-6, 1975. Springer-Verlag: Berlin/Heidelberg/New York, Pp. 296-311, 1975.

Berlin, C.I., Cullen, J.K., Jr., Hughes, L.F., Berlin, H.L., Lowe- Bell, S.S., and Thompson, C.L. Dichotic processing of speech: Acoustic and phonetic variables (acoustic variables in dichotic listening). *Proceedings of a Symposium on Central Auditory Processing Disorders*, Pp. 36-46, January, 1975.

Cullen, J.K., Jr., Berlin, C.I., Hughes, L.F., Thompson, C.L., and Samson, D.S. Speech information flow: A model. **Proceedings of a Symposium on Central Auditory Processing Disorders**, Pp. 108-127, January, 1975.

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Mouney, D.F., Cullen, J.K., Jr., Gondra, M.I., and Berlin, C.I. Tone burst electrocochleography in humans. **Trans. Am. Acad. Ophthalmol. Otolaryngol.** 82(3), 348-355, 1976.

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Berlin, C.I. and Cullen, J.K., Jr. Acoustic problems in dichotic listening tasks. Book Chapter In: S. Segalowitz and F. Gruber (Eds.), Language Development and Neurological Theory, Academic Press, Inc.: New York, New York, Pp. 75-88, 1977.

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Berlin, C.I. Electrophysiological indices of auditory function. Chapter Four In: F. N. Martin (Ed.), Pediatric Audiology, Prentice-Hall, Inc.: Englewood Cliffs, New Jersey, Pp. 113-173, 1978.

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Mouney, D.F., Berlin, C.I., Cullen, J.K., Jr., and Hughes, L.F. Changes in the human eighth nerve action potential as a function of stimulation rate. **Acta Otolaryngol.** 104, 551-554, 1978.

Berlin, C.I. and Dobie, R.A. Electrophysiological measures of auditory function via electrocochleography and brainstem evoked responses. Book Chapter In: W. F. Rintelmann (Ed.), Hearing Assessment, University Park Press: Baltimore, Maryland, Pp. 425-458, 1979.

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Dobie, R.A. and Berlin, C.I. Influence of otitis media on hearing and development. **Ann. Otol. Rhinol. Laryngol.** 88(5), Part 2, Sept.-Oct., 1979.

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Berlin, C.I. Intervention in mild to moderate conductive and sensorineural hearing losses. Birth Defects: Original Article Series, March of Dimes Birth Defects Foundation, 16(4):335-345, 1980.

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Collins, M.J., Cullen, J.K., Jr., and Berlin, C.I. Auditory signal processing in a hearing-impaired subject with residual ultra-audiometric hearing. **Audiology** 20, 347-361, 1981.

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Berlin, C.I. and Shearer, P.D. Electrophysiological simulation of tinnitus. **CIBA Symposium**, Pp. 139-150, 1981.

Gardi, J.N. and Berlin, C.I. Binaural interaction components of the guinea pig ABR: Possible origins. **Arch. Otolaryngol.**, 164-168, 1981.

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Killion, M.C., Berlin, C.I., and Hood, L.J. A low frequency emphasis open-canal hearing aid. **Hearing Instruments** 35, 30-34 and 66, 1984.

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Berlin, C.I. and Hood, L.J. Auditory brainstem response and middle ear assessment in children. Book Chapter In: F. Martin (Ed.), Hearing Disorders in Children. Pro-Ed Publishers: Austin, Texas, 1987.

Shipley-Brown, F., Dingwall, W.O., Berlin, C.I., Yeni-Komshian, G., and Gordon-Salant, S. Hemispheric processing of affective and linguistic intonation contours in normal subjects. **Brain and Lang.** 33, 16-26, 1988.

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Bobbin, R.P., Fallon, M., Li, L. and Berlin, C.I. Guinea pigs show post-natal stability in frequency mapping at the basal turn. **Hearing Research**. 51, 231-234, 1991.

Hood, L.J., Berlin, C.I., and Parkins, C.W. Measurement of Sound. In: J.D. Osguthorpe and W. Melnick (Eds.), Otolaryngologic Clinics of North America, 24(2), 233-251, 1991.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004) Confirmation No. 8615
For: HEARING AID SYSTEM)

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Robert G. Glaser, Ph.D. declares and says that:

1. I am President and owner of Audiology Associates of Dayton, Inc. I have been a practicing Audiologist for over 30 years.
 2. I received my B.S. in Speech Pathology and Audiology in 1969 from Bowling Green State University, my M.A. in Audiology in 1971 from Kent State University, and my Ph.D. in Audiology in 1974 from Kent State University.
 3. I served as President Elect of the American Academy of Audiology from 1998 to 1999, as President of the American Academy of Audiology from 1999 to 2000 and as Past President of the American Academy of Audiology from 2000 to 2001. I also served on the Board of Directors for the American Academy of Audiology from 1995 to 2000. The American Academy of Audiology is the leading professional organization for

Audiologists throughout the United States with a significant and growing international membership.

4. I served on the Board of Directors for Grandview and Southview Hospitals from 1994 to 2000 and as both Executive Director of Research Centers and Chairman of the Institutional Review Board for the same. I served as Director of Neurodiagnostics and Hearing and Balance Centers in Grandview Hospital from 1992 to 2000. I also served as Chairman of the Ohio Board of Speech-Language Pathology and Audiology from 1985-1992, the licensing and regulatory board for Audiologists and Speech-Language Pathologists practicing in the State of Ohio.

5. I have been a Clinical Professor of Audiology at Ohio University School of Osteopathic Medicine since 1985, an Adjunct Professor of Audiology at Miami University since 1983, and Assistant Clinical Professor of Otolaryngology at Wright State School of Medicine since 1977. I was also Assistant Professor of Audiology at Northern Illinois University from 1974-1976.

6. I have published over 40 articles and provided over 90 podium and course presentations on hearing loss, hearing instruments and fitting, vestibular disorders and assessment, practice management, professional education, reimbursement and policy delineation for both state government and national, professional activities. I have authored a book chapter on private practice and hearing instrument dispensing, and am currently co-authoring a textbook on strategic practice management, which is a comprehensive, pragmatic textbook for graduate students in Audiology, professors, new audiologists and seasoned veterans considering re-engineering of their current practice situations.

7. I am fully familiar with Vivatone's open ear hearing aid system and consider it to be a new category in the field of hearing aid systems. I distinguish this category (as a new category) of hearing aid, which includes a behind-the-ear amplifier and a receiver

suspended within the ear canal, from the other categories of hearing aids that have been developed, marketed and sold for more than 30 years. Other categories include completely in canal (CIC) hearing aids, in-the-canal (ITC) hearing aids, in-the-ear (ITE) hearing aids and behind-the-ear (BTE) hearing aids. The first three types (CIC, ITC and ITE) occlude the ear canal by providing electronics either within the ear canal or immediately external to the lumen of the external auditory canal, in the concha portion of the ear. BTE hearing aids do not occlude the ear canal, but instead provide all components in a housing secured behind the ear. The speaker system is internal to the hearing instrument and is connected to the ear canal via an open tube or earmold with or without various degrees of venting in an attempt to reduce the occlusion effect.

The Vivatone open ear hearing aid is different from the other categories described immediately above in that the speaker assembly is externalized from the instrument and is designed to be inserted into the ear canal to optimize the primary benefit of reducing the occlusion effect and likely enabling greater clarity of signal reproduction by virtue of the proximity of the speaker to the tympanic membrane. Additionally, the Vivatone system is not subject to the effects of tube resonance which is not only measurable in the acoustics laboratory but is noted clinically by patient's responses indicating greater clarity in their existing BTE instruments when aged tubing is changed. Since its inception and development the Vivatone hearing system, its small BTE component with internal microphone assembly, thin speaker wire and the small speaker suspended in the ear canal has been and continues to be considered a revolutionary product design by audiologists charged with fitting and following their patients through the course of aural rehabilitation.

9. Since the introduction of the Vivatone hearing aid, other manufacturers have seen fit to produce hearing aids in this category. Siemens, Interton, Oticon, Hansaton and Phonak (see the attached Phonak literature at Exhibit 1) are a few examples of hearing aid manufacturers that have taken the principal element of the Vivatone hearing aid design as described immediately above. These manufacturers may have produced products with additional electronics, software compression, etc., however, the basis of

their offerings in this new class of hearing aids obviously stems from the Vivotone product.

10. I have reviewed Dr. Bauman's patent application and note that Dr. Bauman uses the term "insertion loss" rather than "insertion gain." I note in the background section of Dr. Bauman's application, paragraph 2, which states "Insertion of hearing aid receivers in the ear produces an insertion loss, which reflects a distortion or elimination of the patient's natural or original concha and ear canal resonant characteristics." I also note paragraph 37, which states that "the data analyzed are the values of Probe Real Ear Insertion Response Curve, which consisted of differences between the Probe Real Ear Unaided Response Curve and the Probe Real Ear Aided response curve and the corresponding values repeated while the subject vocalized the letter 'EE'." As an Audiologist, it is clear to me that the "Insertion Effect" test data and the "Insertion Loss" terminology referred to in the specification and the claims refers to the same measurement to determine the effects of electronics or earmold configurations that would reduce the aperture of the lumen of the ear canal. Accordingly, anything that would reduce the cross sectional dimension of the lumen of the ear canal would cause greater insertion loss. The maximum insertion loss would be exemplified by a completely occluded lumen. Read in the light of the specification, the scope of the term "insertion loss" is clear, and the test data is directed to the meaning of "insertion loss" utilized by the claims.

11. It is my understanding that the Patent Examiner refers to FIGURE 11 of Pluvinage and its description of "insertion gain" on Column 8, lines 15-26. I have reviewed Dr. Bauman's patent application and noted that Dr. Bauman teaches "insertion loss" rather than "insertion gain." As an Audiologist, it is clear to me that the "Insertion Effect" test data and the "Insertion Loss" terminology referred to in the specification and the claims refers to a measurement of a profile in the ear canal with all electronics in the hearing aid turned off. As indicated above, anything that would reduce the cross sectional dimension of the lumen of the ear canal would cause greater insertion loss.

Also indicated above, the maximum insertion loss would be exemplified by a completely occluded lumen. Thus, “insertion loss” (as is claimed by Bauman) is not a function of sound pressure levels (SPL). Pluvinage teaches that its configuration (I have already noted how Pluvinage is different by virtue of use of both a speaker and a sound sampling tube side by side in the ear canal) generates less insertion gain at higher SPL (see the charted line for 80 dB relative to the others). This chart does not teach less than about 3dB of “insertion loss” and does not suggest that in a switched off mode, the side-by-side profile would generate less than about 3dB of “insertion loss.” Also, even at 80 dB SPL, for certain frequency ranges, Pluvinage’s “insertion gain” is shown to be greater than 3dB in FIGURE 11.

12. I understand that the Examiner believes that the Knowles EH or FK series speakers describe certain “maximum lateral dimension” particulars of Dr. Bauman’s claims in light of Pluvinage. Pluvinage describes use of the speaker 44 in a receiver 44 in the ear canal. While the Knowles speaker itself may have a metallic casing, it would always practically include a plastic, or the like, housing material provided around the metallic speaker. While it may be possible to discern the Knowles speaker size, there is no clear indication of how much additional volume the Pluvinage receiver housing would consume. Additionally, inclusion of the microphone sampling tube alongside the receiver would increase the “maximum lateral dimension” which could approach 50 percent of the average, maximum lateral dimensions of ear canals.

13. Reference is further made to the Patent Examiner’s rejection of the claims with regard to Pluvinage. The Examiner appears to indicate that the Pluvinage patent teaches that an audiologist possessing ordinary skill in the common art would be motivated and able to modify the hearing aid described by Pluvinage to achieve the Vivotone hearing aid system wherein the only component in the ear canal is the speaker assembly. Pluvinage requires both delivery and sampling of sound within the ear canal. A speaker is placed within the ear canal alongside a tube, which delivers the sampled sound to a monitoring microphone in the external housing of the BTE component. The delivery-

sampling component packaged described by Pluvinage is significantly different from the Vivotone system by virtue of the fact that in Pluvinage, multiple product components are side by side in the ear canal increasing the size of the device section suspended in the ear canal, thus likely adding to the occlusion effect. Additionally, there is the potentially negative effect of tubal resonances, described above. It must also be understood that the proposed modification is not, as described by the Patent Examiner, an obvious modification. With regard to the Patent Examiner's contention that an Audiologist would indeed be motivated to change the design of Pluvinage to avoid infringing patent claims, I can positively state that I would not have known to do this. Audiologists, in general, are neither engineers nor legal or patent experts and would not have considered such an in-office modification as described above to benefit the patients under their care.

14. I also understand that the Patent Examiner has indicated that an audiologist would be motivated to change the CIC device described by U.S. Patent Application Number 20040010181 to Feeley (which is a CIC device that requires use of a mold or a "vented mold" in all cases). Specifically, I understand that the Patent Examiner believes that an audiologist would want to remove the mold and put an eartip (described in U.S. Patent Application Number 2003002700 to Fretz at number 14 in the drawings) around the speaker itself. Fretz simply uses a tube to deliver sound to the ear canal. This is completely different from the Vivotone system and from the Feeley system.

The Vivotone system is not an obvious modification of the Feeley system nor the system described by Fretz. The Feeley system is designed to institute the opposite effect of occluding the ear canal, despite Feeley's suggestion that insertion may, by virtue of the depth of penetration of his earmold design, guarantee eradication of the occlusion effect. Audiologists prefer and apply ear molds with and without a variety of venting strategies for a many reasons predicated on the nature and extent of their patient's hearing loss. Fretz, on the other hand, is different simply because it is solely a tube design.

15. The Examiner further indicated that with regard to Dr. Bauman's claim 58, the GN ReSound Air product has a sport lock feature that is a wire. Neither the ReSoundAir

pamphlet nor the GN ReSound article show a wire sport lock. Based on the cited article and brochure, and based on my personal experience fitting the ReSound Air hearing aid, the sport lock is a flexible plastic.

16. I also understand that the Examiner questions the value of the commercial success and copying indicators from various of Mr. Hirsch's Declarations. It is my opinion that Vivotone created a new category of hearing aid when they launched their Vivotone system. It is also my understanding that they may have lost market share when Oticon, Siemens and others introduced their competing products. The Vivotone product was, in my opinion, a clever design that unequivocally turned heads in the audiology community. The Vivotone system was viewed as a logical and realistic approach to reducing the bane of most hearing aid fittings, the occlusion effect. As such, I am not surprised that despite very little advertising, Vivotone's product sales soared before similar competing products were introduced. These sales occurred despite the fact that most Audiologists have fairly strong ties to certain manufacturer's product lines and despite the fact that Vivotone did very little direct advertising (the industry buzz about Vivotone was predominately by word of mouth). Penetration into the marketplace is also a good indicator of success. It is my opinion that Vivotone has done quite well in the marketplace because of their unique configuration and product presentation (the small BTE component with the microphone port, the thin speaker wire, and the small speaker suspended in the ear canal). For many of these same reasons and others, it is clear to me that other major manufacturers of hearing instruments have seen fit to copy the product.

The Patent Examiner has indicated "hearing aids are not the type of device you see advertised on TV or in popular magazines." Thus implying there is little over-the-counter market available to hearing aid manufacturers, he also indicated that hearing aids are distributed in a controlled manner (much like selling blood pressure or cholesterol lowering medication). Licensing boards for audiologists and commercial hearing aid dealers throughout the country effectively control the manner under which hearing aids are dispensed to the public. That does not, however, reduce the manufacturer's need and activity in marketing their products to audiologists and hearing aid dispensers. The

hearing aid industry is heavily affected by advertising. Marketing to the professional audiologist as well as the consumers is an extremely expensive proposition within the hearing aid industry. As such, Vivotone's commercial success should be seen as even more remarkable because of the fact that Vivotone's advertising expenditures were so minimal.

With regard to the Patent Examiner's comments on market data, the Examiner makes certain comparisons of Vivotone's sales relative to certain categories (0.65% of all hearing aid sales; 1.78% of all BTE units). He also references an article by Kirkwood in the Hearing Journal in which GN ReSound CEO Alan Dozier states "...with all the performance improvements, the question is, why do we continue to get 2%, 3% and 4% growth?" The Vivotone configuration gave rise to a new category of hearing aids that is not comparable with hearing aid sales generally, or with BTE sales specifically. The Patent Examiner also indicates that the Vivotone system's success may be attributed merely to "exploratory success", or curiosity of the consumer, rather than to a "got to have it type of success." This is wholly untrue. The benefits of this configuration are readily understood by audiologists, who, as distributors to consumers, purchase these instruments from the manufacturers. As I noted before, audiologists view the Vivotone configuration as a giant leap forward in the industry. While it may be said generally that some improvements in the hearing aid industry may be "incremental", the Vivotone configuration must be considered "segmental" in that it established an entirely new and interesting offering in the dispenser's clinical armamentarium heretofore not available. Simply put, the Vivotone configuration was a head turner from the start.

The Examiner quoted a comment of Alan Dozier from GN Resound: "Not a lot of consumer advertising is being done to build confidence in hearing instruments and build brand awareness." I agree with this comment with regard to conventional hearing aids. However, I completely disagree that this comment relates to this new category of hearing aids. The Vivotone product has spurred a change in the hearing aid industry as it relates to marketing efforts. Indeed, a great deal of advertising is now being done for this category (a "this is not your father's hearing aid" type of response to the Vivotone

configuration). Exemplary of this are the marketing materials of Oticon, Siemens, Hansaton, Interton and Phonak.

The Patent Examiner also refers to the Kirkwood article, page 14, and equates BTE sales with “open fittings” (“mini-BTEs...most of them using open fittings”). Most of the mini-BTEs were designed to fit hearing losses at moderate-to-severe levels and cannot be used effectively in open canal fittings in that there is a distinct need to reduce the inherent feedback that comes with an open fitting (i.e., traditional tube needs to be occluded in certain circumstances to reduce feedback). This raises another distinction between open tube fittings and the Vivotone system, which places a small, non-occluding speaker in much closer proximity to the tympanic membrane than the BTE using a tube. The Vivotone speaker, because of its proximity to the tympanic membrane, uses much less power. Thus, feedback is much less of a concern, and the ear canal does not need to be occluded. Comparison of the open canal Vivotone system (and the similar Oticon, Hansaton, Siemens, etc. systems) with conventional BTE tube systems is, accordingly, really not effective (it is the “apples to oranges” comparison).

The above also relates to the Patent Examiner’s assertion that GN ReSound “pioneered” the open fitting. Again, the comparison of BTE tube systems (like the ReSound Air hearing instrument) and the Vivotone open canal receiver system is really not proper. Whether or not ReSound pioneered open tube based systems is really not relevant to the category of hearing instruments containing the Vivotone hearing instrument. Also, as described above, the Pluvinage instrument also does not compare. The Vivotone system is an advancement in that it rejects BTE-tube designs as well as the hybridized tube design of Pluvinage.

I declare under penalty of perjury that the foregoing is true and correct.

January 18, 2007

Robert G. Glaser, Ph.D

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I declare under penalty of perjury that the foregoing is true and correct.



January 18, 2007

Robert G. Glaser, Ph.D.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bauman et al.)
Serial No. 10/773,731) Group Art Unit: 2643
Filed: February 5, 2004)
For: HEARING AID SYSTEM) Confirmation No. 8615

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Sir:

Dr. Natan Bauman declares and says that:

1. I am an inventor of the above-referenced application. I have been intimately involved in the development and manufacture of the open ear hearing aid system, which includes a behind the ear unit coupled to an open ear speaker within the ear canal.

2. The above-referenced application describes and claims an open ear hearing aid system, including a behind-the-ear amplifier and a receiver suspended within the ear canal, which receiver has an architecture that provides what I generally refer to as an "open ear configuration". More specifically, the application describes and claims, in part:

a hearing aid system, comprising:

a microphone sampling position located externally of an ear canal of a user,

a receiver comprising a speaker positioned in an open ear configuration and suspended within said ear canal, wherein sound from the microphone sampling position is amplified in accordance with hearing loss programming and passed via electrical connection around a portion of the external ear and through the ear canal opening to the speaker that is positioned within the ear canal in an

open ear configuration, wherein said microphone sampling position and an amplifier are positioned within a behind the ear unit.

Additionally independent claim 1 further requires that the receiver generate about three decibels or below of insertion loss over a portion of human ear audible frequencies.

3. What is referred to as "insertion loss" in the specification and claims, and what was referred to as "insertion effort" in the cited test data, is not "insertion gain." That is, the entire specification, including the test data, describes and claims "insertion loss", whereas the insertion loss is measured with the hearing instrument in place within the canal, but turned off. It is a comparison of the Real Ear Unoccluded Response Curve (completely unaided) with the Real Ear Occluded Response Curve (hearing aid in place, but switched off).

I declare under penalty of perjury that the foregoing is true and correct.


Nathan Bauman

March 13, 2007

NHS-0010

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